# EXHIBIT A

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION | |
| This document relates to: | |
| | MDL No. 2804 |
| *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45090 | Hon. Dan Aaron Polster |
| *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 17-op-45004 | |

# Expert Report of Carlos Aquino

**June 6, 2019**

**Contents**


I. Introduction ..... 1

II. Qualifications ..... 1

III. Scope and Summary of Opinions ..... 4

IV. Materials Considered ..... 6

V. Regulatory Landscape ..... 7

A. Controlled Substances Act ..... 7

B. Regulations Issued under the CSA ..... 11

C. The Requirements Not Imposed by the CSA and the Regulations ..... 24

D. DEA Audits Registrants to Assess Their Regulatory Compliance ..... 31

E. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 Did Not Weaken DEA's Enforcement Capabilities ..... 34

VI. What is Diversion? ..... 37

A. Definition of Diversion ..... 37

B. Primary Causes of Diversion ..... 38

C. The Vast Majority of Orders Meeting the Regulatory Definition of "Suspicious Orders" Are Legitimate and Not Likely to be Diverted ..... 42

VII. McKesson's Section 55 Suspicious Order Monitoring Program Complied with the CSA and Regulations ..... 44

A. Overview of McKesson's Section 55 Program ..... 44

B. McKesson's Daily and Monthly DU-45 Reports Satisfied the CSA and Regulatory Requirements ..... 47

C. DEA Approved of Distributors Submitting Suspicious Order Reports to DEA After Shipping the Order ..... 50

D. McKesson's Section 55 Program Complied with the CSA and Regulations ..... 52

E. McKesson's Section 55 Program Followed Models of Industry and DEA Approved of Industry Practice ..... 53

VIII. Diversion Trends and Changing Technology ..... 59

A. Rise of Rogue Internet Pharmacies ..... 60

B. Rise of Pill Mills ..... 61

C. Improvements in Technology Used for Anti-Diversion Efforts ..... 61

D. The CSA and Its Regulations Have Not Changed ..... 62

IX. DEA Only Offered Informal Guidance in Response to Changing Diversion Trends and Advancements in Technology ..... 63

A. DEA's Distributor Initiative ..... 63

B. DEA's New Guidance: Transitioning from Excessive Purchase Reporting to Suspicious Order Monitoring ..... 67

C. DEA's New Guidance During the Distributor Initiative Resulted in Confusion Within the Industry ..... 80

X. McKesson's Suspicious Order Monitoring Program Changed in Response to Evolving Diversion Trends and Changing DEA Guidance ..... 85

A. McKesson's LDMP Program ..... 85

B. McKesson's 2008 Controlled Substance Monitoring Program ..... 89

C. McKesson's Enhanced Controlled Substance Monitoring Program from 2013 to Present ..... 95

XI. McKesson Settlement Agreements ..... 98

A. 2008 Settlement Agreement ..... 99

B. 2017 Settlement Agreement ..... 100

XII. DEA Rarely Relied On or Used Suspicious Order Reports ..... 102

A. DEA Rarely Used Suspicious Order Reports ..... 102

B. Submission of Additional Suspicious Order Reports by Distributors Would Not Likely Have Helped Combat Diversion ..... 104

C. ARCOS Provided DEA Extensive Information ..... 105

XIII. Distributors Do Not Possess DEA's Law Enforcement Powers ..... 111

A. Distributors Have Limited Information ..... 111

B. Distributors Do Not Possess Law Enforcement Powers ..... 113

C. Distributors Cannot Police the Closed System of Distribution ..... 114

XIV. Response to the Expert Report of James Rafalski ..... 118

A. Mr. Rafalski's Assumption That McKesson Did Not Conduct Due Diligence Is Incorrect ..... 118

B. Mr. Rafalski's Assumption That Recent Policy Interpretations Were Always in Place Is Incorrect ..... 120

C. The Five Methodologies That Found Over 90% of Orders Shipped into Cuyahoga and Summit Counties Are Suspicious Contradicts Reality ..... 120

D. Any Lack of Suspicious Order Reports Does Not Contribute to Diversion ..... 121

XV. Response to the Expert Reports of Seth Whitelaw ..... 123

A. DEA Does Not Use or Rely on the Federal Sentencing Guidelines When Evaluating Suspicious Order Monitoring Programs ..... 123

## I. Introduction

1. My name is Carlos Aquino. From 1997 through 2009, I worked as a Diversion Investigator and as a Diversion Group Supervisor in DEA's Philadelphia Field Division. I am the founder of PharmaDiversion LLC, a compliance consulting firm specializing in federal laws and regulations relating to the manufacture and distribution of pharmaceutical Schedule II-V controlled substances and regulated chemical products.

2. This report contains my opinions on issues relating to the distribution of pharmaceutical controlled substances and diversion of controlled substances from legitimate sources, including, among other things, DEA's efforts to combat such diversion, and the scope of distributors' duties under applicable federal laws and regulations to maintain effective controls against such diversion. In addition, I have been asked to review and respond to certain opinions expressed by James Rafalski and Seth Whitelaw. My opinions are based on my knowledge, skill, experience, education, and training, as well as my investigation and study of relevant materials. I reserve the right to supplement my opinions based on additional evidence or information that is made available to me after the date of this report.

3. I am being compensated $245 per hour for my time spent working on issues in this case. I am also being reimbursed for any reasonable and customary expenses associated with my work and testimony. My compensation does not depend on the outcome of this matter or the opinions that I express.

## II. Qualifications

4. My background, qualifications, and experience relevant to the issues in this case are summarized below. A copy of my curriculum vitae is attached as Appendix A to this report.

5. I worked for the Philadelphia Police Department for 24 years from March 1971 through January 1995. I began my career as a police officer, and I was later promoted to the

rank of sergeant. While working for the Department, I earned a Bachelor of Arts degree in Criminal Justice from Temple University in May 1981. From 1985 through 1995, I was assigned to the Philadelphia DEA Task Force. In this role, I supervised and performed undercover investigations into illicit drug activities, including the illicit distribution of pharmaceutical controlled substances.

6. I began working full-time at DEA in January 1995, immediately after I retired from the Philadelphia Police Department. I was assigned to the Philadelphia DEA Division Asset Forfeiture Unit as a Legal Technician to handle assets seized from the subjects of federal DEA investigations. These assets, which included cars, boats, and other high value items, were proceeds obtained from illicit drug activities.

7. In July 1997, I became a Diversion Investigator in DEA's Philadelphia Field Office. I attended Basic Diversion Investigator Training at the Xerox Training Center in Lynchburg, Virginia. This program involved 12 weeks of intensive training on federal laws and regulations pertaining to controlled substances and regulated chemicals, regulatory on-site inspections, and administrative and civil investigations involving pharmaceutical controlled substances.

8. As a Diversion Investigator, I worked to make sure that manufacturers, distributors, pharmacies, and physicians followed federal laws and regulations. I participated in unannounced inspections of regulated facilities, which focused on recordkeeping and physical security of controlled substances or regulated chemicals. For example, during inspections of distributor facilities, I would review records to ensure that distributors were verifying DEA registrations and state licenses for pharmacy customers, and I would verify the security of vaults and cages containing controlled substances or regulated chemicals.

9. In March 2004, I attended a DEA special operations training program covering Internet pharmacy investigations. Not long after that, I became involved in Operation Cyberchase, which was a year-long investigation into international Internet pharmaceutical traffickers. Operation Cyberchase was an operation that is now public that targeted traffickers who shipped Schedule II-V controlled substances directly to buyers without physicians conducting medical examinations. These traffickers distributed drugs internationally using rogue Internet pharmacies and used over 200 websites to illegally distribute controlled substances. Eighteen federal agencies in the US along with state Attorneys General and various law enforcement organizations from Australia, Canada, Costa Rica, and India took part in the operation. The operation resulted in more than 23 indictments and 20 convictions. DEA's Philadelphia Field Office played a key role in breaking open this investigation.

10. After working as a DEA Diversion Investigator for eight years, I was promoted in July 2005 to be a Diversion Group Supervisor in DEA's Philadelphia Field Office. I supervised a staff of eleven DEA employees, including diversion investigators, intelligence analysts, and investigative assistants. In this role, I managed complex pharmaceutical investigations that resulted in civil and criminal actions by federal, state, and local prosecutors. In May 2007, I attended the Instructor Developmental Course at DEA's Training Center in Quantico, Virginia. During this three week course, I received guidance on how to provide effective training to diversion investigators and special agents assigned to DEA's Office of Diversion Control. I retired from DEA in January 2009.

11. After retiring from DEA, I founded PharmaDiversion LLC, which is a compliance consulting firm that specializes in federal laws and regulations that govern the manufacture and distribution of Schedule II-V controlled substances.

12. My clients include manufacturers, distributors, importers/exporters, hospitals/clinics, labs, researchers, pharmacies, and practitioners. I work to make sure that my clients comply with federal laws and regulations, including the Controlled Substances Act and its regulations. I also provide training programs designed to meet the needs of various DEA registrants. With my work as an industry consultant, I maintain an understanding of DEA's policies, practices, and expectations regarding diversion control and regulation.

13. I am a member of a number of professional organizations, including the National Association of Drug Diversion Investigators ("NADDI"). NADDI is the nation's leading drug diversion training organization and is the largest networking platform for professionals involved in the field of pharmaceutical drug diversion. I am also a member of the National Association of State Controlled Substances Authorities ("NASCSA"), which is an organization that identifies and develops strategies to reduce the abuse, misuse and diversion of controlled substances. I have listed in my curriculum vitae additional professional organizations with which I am or have been affiliated.

## III. Scope and Summary of Opinions

14. Counsel for McKesson have asked me to share my opinions and provide expert testimony on certain topics. I have provided a brief overview of the scope of my opinions in this section. My complete and detailed opinions on these topics can be found in my report.

15. In my report, I provide an overview of the regulatory structure that governs the distribution of controlled substances. I explain the requirements imposed on distributors by the Controlled Substances Act, including the "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial

channels."[1] I also discuss what requirements are not imposed on distributors under the CSA. My report then provides an overview of what is required by regulations issued under the CSA, and I walk through what is not required under the regulations.

16. Then, I describe McKesson's Section 55 Suspicious Order Monitoring Program. I walk through the elements of McKesson's Section 55 program and its submission of DU-45 reports to DEA. I also explain how McKesson's Section 55 program followed the generally-accepted models of industry and reflected guidance that distributors received from DEA.

17. My report then provides context for the changes to McKesson's suspicious order monitoring program over the past 20 years. I describe the rise of rogue Internet pharmacies and pill mills, and explain how McKesson continually enhanced its programs to respond to these trends. I also explain how advances in technology over the last 20 years have been incorporated into McKesson's suspicious order monitoring programs.

18. I also explain how DEA's guidance to distributors shifted beginning with DEA's Distributors Initiative Program, which focused on the rise of rogue Internet pharmacies, through the letters written by Joseph Rannazzisi and the presentation at the 2007 Pharmaceutical Industry Conference in Houston held by DEA. The report also explains how DEA's guidance to distributors changed on the issue of whether distributors should "block" or not ship an order that meets the definition of a suspicious order.

19. My report then walks through how McKesson's suspicious order monitoring programs adapted in response to diversion trends and changing DEA guidance. I provide an overview of McKesson's Lifestyle Drug Monitoring Program, the 2008 Controlled Substance Monitoring Program, and the enhancements to McKesson's Controlled Substance Monitoring

[1] 21 U.S.C. § 823(b).

Program. I also offer my opinions on McKesson's 2008 and 2017 Settlement Agreements. I also explain that lack of submission of suspicious order reports by McKesson did not contribute to diversion because, in my experience, DEA rarely relies on suspicious order reports and because DEA possessed extensive information through its ARCOS database.

20. My report next explains that distributors, unlike DEA, are unable to police the closed system of distribution. I explain that distributors lack DEA's law enforcement powers and distributors do not possess the same information as DEA, such as information regarding the doctor-patient relationship.

21. I conclude my report by offering my response to certain opinions offered by Plaintiffs' witnesses James Rafalski and Seth Whitelaw.

## IV. Materials Considered

22. My opinions are based upon my review of documents in this case, as well as upon my knowledge, skills, training, experience, and education as a police officer, DEA Diversion Investigator, DEA Diversion Group Supervisor, and consultant for over 40 years. A list of the materials that I considered in forming my opinions is attached as Appendix B.

23. After the submission of my expert report, I may amend my opinions based upon additional information that is made available to me in the future. I also reserve the right to: (1) rely on supplemental materials that are produced during this litigation; (2) respond to any report filed by Plaintiffs' expert(s) relating to the issues I have discussed in this report and any expert reports that I have not reviewed, (3) submit a supplemental expert report based on further analysis of additional evidence or information, and (4) make additions, deletions, or modifications in the future that would be reflected in my trial testimony.

## V. Regulatory Landscape

### A. Controlled Substances Act

24. I am looking to the Controlled Substances Act, which is commonly referred to as the "CSA," and the regulations issued under the CSA to explain the regulatory responsibilities of distributors.[2] Relevant requirements of the CSA and its regulations have stayed essentially the same since the 1970s.[3] Even though the CSA and the corresponding regulations have remained unchanged, diversion trends have continually changed over the last 40 years.

25. DEA is the federal agency responsible for enforcing the CSA,[4] and DEA controls the closed system for drug distribution in the US.[5] As Joseph Rannazzisi testified to Congress,

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[2] 21 U.S.C. § 801 et seq.; 21 C.F.R. § 1301.01 et seq.

[3] Joseph Rannazzisi ("Rannazzisi") Tr. (Apr. 26, 2019) at 68:1-11 ("Q. The way distributors report suspicious orders to the DEA has changed in the last 40 years-plus since 1971; isn't that correct? . . . THE WITNESS: I would say that the regulation hasn't changed."); Thomas Prevoznik ("Prevoznik") Tr. (Apr. 17, 2019) at 90:10-13 ("Q. And have either [21 U.S.C. § 823] or [21 C.F.R. § 1301.74] been amended or altered since 1971 to your knowledge? A. No, they have not."); Prevoznik Tr. (Apr. 18, 2019) at 661:15-18 ("Q. And has [21 C.F.R. § 1301.74] materially changed since it was originally enacted in 1971? A. No."); Prevoznik Tr. (May 17, 2019) at 820:2-5 ("Q. And is [21 C.F.R. § 1301.74(b)] the same in all meaningful ways to what it looked like when it was enacted in 1971? A. Yes."); Demetra Ashley ("Ashley") Tr. at 28:7-12 ("Q. To your knowledge, has [§ 1301.74(b)] ever changed since it was promulgated in 1971? … A. I don't think so.").

[4] Pursuant to 21 U.S.C. § 871(a), the Attorney General has delegated administration and enforcement of the CSA to the Administrator of DEA. Rannazzisi Tr. (Apr. 26, 2019) at 49:24-50:1 ("Q. It's true that DEA controls the closed system of drug distribution, right? A. Yes."); Kyle Wright ("Wright") Tr. (Mar. 4, 2019) at 297:6-14 ("[A.] I'll try to say it in a nutshell: to maintain, oversee and protect the closed system of distribution at all levels. … Q. Was that the role of the Drug Enforcement Agency [sic], as you understood it in your experience? A. Yes, sir."); Rannazzisi Tr. (Apr. 26, 2019) at 58:21-59:3 ("The regulation change would be under the authority of the administrator of the Drug Enforcement Administration and Department of Justice. … [T]he final decision [to change a CSA regulation] is [up to] the Department of Justice and the Drug Enforcement Administration leadership.").

[5] James Rafalski ("Rafalski") Tr. (May 13, 2019) at 346:4-13 ("Q. But you agree that DEA is the agency in the federal government that has authority and responsibility for the controlled system of drug distribution in this country, correct? A. In -- yes, sir. In regards to the regulation,

DEA "register[s] all persons who handle them [i.e., Schedule II substances]; we inspect the documentation of their distribution; we control their import and export; and we control the amount produced, bought, sold, and otherwise transferred."[6] The controls in the CSA "allow DEA to monitor and regulate a controlled substance and its movement."[7]

26. The CSA, which was signed into law in 1970, is the federal law that controls the import, manufacture, distribution, and possession of controlled substances. The CSA created a "closed loop system" of distribution of controlled substances. As part of the closed loop system of distribution, every manufacturer, distributor, pharmacy, and prescriber in the supply chain that handles controlled substances must be registered with DEA.[8] DEA must approve the applications for controlled substance registrations before these entities and individuals are permitted to handle controlled substances.[9] And, because DEA approves the registrations for handling controlled substances, other registrants are permitted to rely on DEA's approval of the

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they're delegated that by the Attorney General, by Congress to the Attorney General, so I agree with that statement, yes, sir.").

[6] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[7] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[8] 21 U.S.C. § 822(a); Rafalski Tr. (May 13, 2019) at 383:12-17 ("Q. Now, it's true that each pharmacy, distributor and manufacturer must register with the DEA in order to lawfully handle controlled substances in the closed system of distribution, correct? A. Yes, sir."); Rannazzisi Tr. (Apr. 26, 2019) at 51:2-8 ("Q. It's true the DEA registers all manufacturers, distributors, pharmacies and doctors that handle Schedule II controlled substances? A. That's true. If -- if their registration allows them to handle Schedule IIs, yes.").

[9] Rannazzisi Tr. (Apr. 26, 2019) at 52:10-53:2 ("Q. When deciding to grant registration to a manufacturer, distributor, pharmacy or doctor, the DEA inspects documentation from each of these potential registrants, correct? … THE WITNESS: Yes. … Q. And all of the materials that each of these potential registrants submits with their application, correct? A. Yes.").

registration when complying with their obligations.[10] DEA also controls the amount of Schedule II controlled substances entering the closed loop system of distribution by setting annual quotas for the particular controlled substances.[11]

27. The CSA establishes five schedules of controlled substances, which are labeled Schedule I, Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances.[12] The determination of what schedule a substance is assigned is based on various factors, including whether the substance has a currently accepted medical use in treatment in the United States, the substance's relative abuse potential, and the likelihood the substance may cause dependence when abused.[13] Common prescription opioids, including those containing fentanyl and oxycodone, are typically classified under Schedule II. Hydrocodone combination products are

[10] Rafalski Tr. (May 13, 2019) at 386:5-25 ("Q. My apologies for that. It's true that distributors are to rely on active DEA registrations when complying with 1301.74(a)? A. Yes, sir. They are required by regulation to make a good-faith effort to confirm that the person that they're going to distribute drugs to has a valid DEA registration."); 21 C.F.R. § 1301.74(a) ("Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance."); Diversion Investigators Manual, 04/16/1996 (CAH_MDL2804_02203353 at -3356) ("DEA field offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship controlled substances.").

[11] 21 C.F.R. § 1303.11; Stacy Harper-Avilla ("Harper-Avilla") Tr. (Apr. 11, 2019) at 43:6-10 ("Q. DEA sets aggregate production quotas for each individual class of controlled substances; is that fair? A. DEA sets quota for each class of Schedule I or Schedule II controlled substance."); Rannazzisi Tr. (Apr. 26, 2019) at 30:12-15 ("Q. DEA established quotas for controlled substances for each year, didn't they? A. Yes, sir.").

[12] DEA, Drug Scheduling, *available at* https://www.dea.gov/drug-scheduling.

[13] DEA, Controlled Substances Schedules, *available at* https://www.deadiversion.usdoj.gov/schedules/.

now listed under as a Schedule II narcotic, but hydrocodone combination products were listed under Schedule III until 2014.[14]

**1. "Controlled Substance" Definition from 21 U.S.C. § 802(6)**

28. The CSA provides definitions for certain terms that are used in the statute. A "controlled substance" is defined by the CSA as "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986."[15]

**2. Requirements for Distributors under 21 U.S.C. § 823(b) and (e)**

29. Section 823 states that the Attorney General shall register an applicant to distribute controlled substances, unless she determines that the issuance of such registration is inconsistent with the public interest based on various factors, including "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[16] As described below, the reference in Section 823 to evaluating whether a prospective distributor is maintaining "effective controls against diversion of particular controlled substances" was historically understood to refer to a distributor's compliance with the detailed physical security of controlled substances and recordkeeping requirements for controlled substances.

[14] Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 79 Fed. Reg. 49,661, 49,682 (Aug. 22, 2014).

[15] 21 U.S.C. § 802(6).

[16] 21 U.S.C. § 823(b).

### 3. Record Retention Requirements under 21 U.S.C. § 827

30. Section 827(a) requires that registrants must make a complete inventory of all relevant controlled substance stocks on hand when (1) the registrant first becomes licensed, (2) the Attorney General classifies as controlled a substance that was not previously considered controlled, and (3) every second year after that.[17] Registrants are required to keep and maintain biennial inventory or other inventory records required under the statute for "at least two years."[18] This retention requirement applies only to inventory records.

## B. Regulations Issued under the CSA

### 1. Regulatory Definitions under 21 C.F.R. § 1300.01

31. The regulations issued under the CSA provide definitions of various entities within the closed system of distribution, including definitions for "dispenser," "manufacturer" and "pharmacist."[19] The regulations do not include definitions for "distributor" or "prescriber."

32. According to 21 CFR § 1300.01, a "manufacturer" is "a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst."[20]

33. A "pharmacist" is "any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State."[21]

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[17] 21 U.S.C. § 827(a).

[18] 21 U.S.C. § 827(b).

[19] 21 C.F.R. § 1300.01.

[20] 21 C.F.R. § 1300.01.

[21] 21 C.F.R. § 1300.01.

34. A "dispenser" is "an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance."[22]

**2. Registration Requirements under 21 C.F.R. § 1301.11**

35. Section 1301.11 requires entities that want to join the closed loop system of distribution to register with DEA. The regulation requires that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26."[23]

36. Prior to registration, DEA conducts an on-site preregistration inspection.[24] This inspection is usually only conducted for manufacturers, distributors, importers, exporters, and

[22] 21 C.F.R. § 1300.01.

[23] 21 C.F.R. § 1301.11(a).

[24] Rafalski Tr. (May 13, 2019) at 383:22-384:7 ("Q. The DEA then conducts an on-site inspection of each applicant's facilities, correct? A. They do not conduct on-site investigations of pharmacies, at least not in the Detroit division. Q. Your testimony here today is that they conduct on-site inspections of distributors? A. Yes, sir, and manufacturers prior to approval of a registration."); Rafalski Tr. (May 14, 2019) at 640:14-22 ("Q. You mentioned pre-reg. Is that a preregistration inspection by the DEA? A. Yeah, I'm sorry, that's kind of a term. Yes, sir, that's going on-site and prior to issuing the DEA registration, making sure that you're confident that the registrant is in compliance with the regulations and has an understanding before you issue the DEA registration."); Diversion Investigators Manual, 9/20/2011 § 5012.5 (CAH_MDL2804_00953317 at -3331) ("Preregistrant investigations reduce the possibility of registering unauthorized subjects, ensure that the means to prevent diversion are in place, and determine whether registration is consistent with the public interest. Preregistrant investigations must be conducted at the earliest possible time following receipt of the application by the Division.").

analytical labs, and researchers.[25] An inspection is conducted for pharmacies only in some offices.[26]

37. All registration applications must be submitted for filing to the Registration Unit at DEA.[27] The regulation provides that DEA may inspect, or cause to be inspected, the establishment of an applicant for registration or a registrant.[28] The regulation also provides that DEA will review the application for registration to determine whether the applicant has met the standards of the CSA.[29]

### 3. Security Requirements under 21 C.F.R. § 1301.71-1301.76

38. Sections 1301.71 through 1301.76 establish "security requirements" to guard against theft and diversion of controlled substances. These particular regulations focus on physical security controls and operating procedures. When members of DEA's field offices

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[25] Diversion Investigators Manual, 6/11/2012 § 5221.3 (CAH_MDL2804_00953317) at -3446 ("An on-site investigation is required for each applicant who proposes to **manufacture, distribute, import, or export** controlled substances in any schedule, or **manufacture, distribute, import or export** list I chemicals, or to treat for opiate addiction." (emphasis added)); Rafalski Tr. (May 13, 2019) at 383:18-384:15 ("Q. Each pharmacy, distributor and manufacturer must submit an application to DEA? A. Yes, sir. Q. The DEA then conducts an on-site investigation of each applicant's facilities, correct? Q. They do not conduct on-site investigations of pharmacies, at least not in the Detroit division. Q. Your testimony here today is that they conduct on-site investigations of distributors? A. Yes, sir, and manufacturers prior to approval of a registration. Q. Why doesn't the DEA conduct on-site inspections of pharmacies? … A. On advice of my counsel, I'm not going to answer that question."); Rafalski Tr. (May 13, 2019) at 386:5-15 ("Q. … You would agree that DEA conducts diligence, reviews applications, looks at the background of these applicants so that distributors can rely on the DEA registrations when complying with 1301.74(a)? … A. So if your question is in regards to pharmacies, they don't conduct those types of investigations ….").

[26] Rafalski Tr. (May 13, 2019) at 383:22-384:2 ("Q. The DEA then conducts an on-site inspection of each applicant's facilities, correct? A. They do not conduct on-site investigations of pharmacies, at least not in the Detroit division.").

[27] 21 C.F.R. § 1301.14(a).

[28] 21 C.F.R. § 1301.31.

[29] 21 C.F.R. § 1301.31.

conducted unannounced inspections of distribution centers, these security requirements were an important focus of the audit and inspection.[30] I will discuss §§ 1301.71, 1301.72, 1301.73, 1301.75, and 1301.76, before turning back to § 1301.74.

**a) Security Requirements in Section 1301.71**

39. Section 1301.71 outlines requirements to which registrants must adhere to maintain a registration.[31] Section 1301.71, titled "Security requirements generally" (the "Security Requirement") states:

> (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion….[32]

In determining whether a registrant meets the "security requirement," Section 1301.71(b) provides a standard of "substantial compliance," not strict compliance, to the registrant:

> (b) Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the

[30] Diversion Investigators Manual, 5/18/1993 § 5012.1 (CAH_MDL_PRIORPROD_DEA07 01176247-R) at -6263-R ("Cyclic investigations serve as a deterrent to diversion through the continuous evaluation of registrants' recordkeeping procedures, security, and general adherence to the Controlled Substances Act."); Diversion Investigators Manual, 9/20/2011 § 5012.1 (CAH_MDL2804_00953317 at -3329).

[31] Rannazzisi Tr. (May 15, 2019) at 411:10-15 ("So the Controlled Substances Act and the regulations specifically outline who is a registrant and what their requirements are to maintain a registration and all DEA registrants must maintain effective controls against diversion. That's 1301.71.").

[32] 21 C.F.R. § 1301.71(a).

> following factors as he may deem relevant to the need for strict compliance with security requirements[.][33]

40. Section 1301.71(b) also outlines fifteen factors that DEA may consider in determining whether a registrant is in "substantial compliance" with the security requirements set forth in Sections 1301.72 through 1301.76.[34] The fifteen factors focus on procedures concerning the physical security of controlled substances. To determine substantial compliance, for example, DEA considers factors such as a building's characteristics, the vault system, key control systems, alarm systems, public and employee access to and within the facility, and recordkeeping practices.[35]

**b) Security Requirements in Section 1301.72**

Section 1301.72(a) provides non-practitioners with detailed physical storage requirements for Schedule I and II controlled substances in safes, steel cabinets, and vaults. I am familiar with these physical security requirements because they were a primary focus of DEA's inspections of controlled substance distribution centers and remain so to this day. The regulations governing vaults constructed after September 1, 1971, illustrate the detailed and specific guidance provided in the law:

> (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with \1/2\-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

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[33] 21 C.F.R. § 1301.71(b); Prevoznik Tr. (Apr. 17, 2019) at 396:9-18 ("Q. So [1301.74](b) states substantial compliance with the standards set forth, right? A. Yes. Q. Okay. And that could be deemed sufficient, correct? A. Yes. That's what it says. Q. It does not say strict compliance, correct? A. Correct.").

[34] 21 C.F.R. § 1301.71(b).

[35] 21 C.F.R. § 1301.71(b)(5)-(11), (14).

> (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
>
> (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
>
> (iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;
>
> (v) The door of which vault is equipped with contact switches; and
>
> (vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.[36]

**c) Security Requirements in Section 1301.73**

41. Section 1301.73 is directed at manufacturers and compounders, and the regulation details security requirements for the storage and retention of in-process controlled substances.[37] It describes requirements for the area or areas in which manufacturing activities with controlled substances shall be conducted.[38] For example, the area must only have "limited access," and continuous surveillance of the area must be maintained.[39]

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[36] 21 C.F.R. § 1301.72(a)(3).

[37] 21 C.F.R. § 1301.73(a).

[38] 21 C.F.R. § 1301.73(b).

[39] 21 C.F.R. § 1301.73(b).

**d) Security Requirements in Section 1301.75**

42. Section 1301.75 provides security requirements for practitioners, and the security requirements vary for controlled substances of different schedules.[40] For example, Schedule I controlled substances shall be stored in a "securely locked, substantially constructed cabinet."[41] Schedule II-V controlled substances, on the other hand, should also be stored in a securely locked, substantially constructed cabinet, but may, under some circumstances, be dispersed throughout a stock of noncontrolled substances so as to obstruct theft or diversion.[42]

**e) Security Requirements in Section 1301.76**

43. Section 1301.76 provides additional security controls for practitioners.[43] Under this section, registrants must not employ anyone with access to controlled substances who has been convicted of a felony offense related to controlled substances or had an application with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause.[44] Registrants are also required to notify the relevant DEA Field Division Office of the theft or significant loss of any controlled substances within one business day of discovery of such theft or loss.[45] The section also requires that registrants acting as distributors comply with requirements applied to distributors, even if they are not registered as such.[46]

[40] 21 C.F.R. § 1301.75(a), (b).
[41] 21 C.F.R. § 1301.75(a).
[42] 21 C.F.R. § 1301.75(b).
[43] 21 C.F.R. §1301.76.
[44] 21 C.F.R. § 1301.76(a).
[45] 21 C.F.R. § 1301.76(b).
[46] 21 C.F.R. §1301.76(c).

### f) Section 1301.74(a)'s "Good Faith Inquiry" Security Requirement

44. 21 CFR § 1301.74 contains further security requirements for controlled substances. Section 1301.74 is titled "other security controls for non-practitioners."

### g) Section 1301.74(a) requires only a "good faith inquiry" into a customer's registration

Section 1301.74(a) requires a registrant to conduct "a good faith inquiry" to determine if its customer is registered to handle controlled substances.[47] The good faith inquiry in Section 1301.74(a) is the only diligence requirement in the CSA and its regulations.[48] Section 1301.74(a) states:

> Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is required to possess the controlled substance.[49]

45. A registrant satisfies § 1301.74(a) if it makes a good faith inquiry with DEA or with the appropriate state agency to make sure that the person or entity who will be receiving the

[47] 21 C.F.R. § 1301.74(a).

[48] 21 U.S.C. § 823; 21 C.F.R. § 1301.74; Rafalski Tr. (May 13, 2019) at 386:18-387:4 ("Q. It's true that distributors are to rely on active DEA registrations when complying with 1301.74(a)? A. Yes, sir. … Q. And that's actually the only requirement under Section 1301.74(a), correct? A. Yes, it is."); Rafalski Tr. (May 13, 2019) at 348:2-10 ("Q. Is there anything beyond Section 1301.74(b)? A. Well, there's many. There's a security requirement just prior to that where it requires a registrant to make a good faith -- a good-faith inquiry before distributing a controlled substance to ensure that the person has a -- as a registrant has a valid DEA registration."); Prevoznik Tr. (May 17, 2019) at 1214:5-13 ("Q. And the statute and regulation do not specifically speak to due diligence, correct? … A. No. …"); Prevoznik Tr. (May 17, 2019) 1214:21-12:15:1 ("Q. Are you aware of the phrase 'due diligence' being in either the statute or the regulation? … A. It's not."); Ashley Tr. at 214:21-216:4 ("Q. Do you know if due diligence is codified anywhere? A. No. …").

[49] 21 C.F.R. § 1301.74(a).

controlled substances holds the proper registrations.[50] A good faith inquiry by a distributor to determine that a customer has a valid DEA registration is the only requirement of § 1301.74(a).[51] Indeed, DEA instructs Diversion Investigators that registrants are to rely on DEA's registration database to satisfy the diligence requirement of Section 1301.74(a):

> DEA field offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship controlled substances.[52]

46. Other than the "good faith inquiry" outlined in § 1301.74(a), the CSA and regulations contain no further due diligence requirements.[53] There is no requirement in this

[50] 21 C.F.R. § 1301.74(a); Rafalski Tr. (May 13, 2019) at 386:18-25 ("It's true that distributors are to rely on active DEA registrations when complying with 1301.74(a)? A. Yes, sir. They are required by regulation to make a good-faith effort to confirm that the person that they're going to distribute drugs to has a valid DEA registration."); Diversion Investigators Manual § 5126, 4/16/1996 (CAH_MDL2804_02203353 at -3356) ("DEA field offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship controlled substances.").

[51] 21 C.F.R. § 1301.74(a); Rafalski Tr. (May 13, 2019) at 387:1-4 ("Q. And that's actually the only requirement under Section 1301.74(a), correct? A. Yes, it is.").

[52] Diversion Investigators Manual § 5126, 4/16/1996 (CAH_MDL2804_02203353 at -3356).

[53] 21 U.S.C. § 823; 21 C.F.R. § 1301.74; Prevoznik Tr. (Apr. 17, 2019) at 216:16-217:18 ("Q. And there's no requirement for distributors and manufacturers to document their 'know your customer' process, correct? … THE WITNESS: There's not a written -- written requirement -- regulation or requirement of that. …"); Prevoznik Tr. (May 17, 2019) at 1212:13-19 ("Q. And I believe that you indicated that there was not any sort of requirement by the DEA of the maintenance of due diligence files, correct? … THE WITNESS: Yes."); Prevoznik Tr. (May 17, 2019) at 1214:5-13 ("Q. And the statute and regulation do not specifically speak to due diligence, correct? … THE WITNESS: No. I mean, they do, because they're saying you have to have effective means to guard against diversion. So that's the guide."); Prevoznik Tr. (May 17, 2019) at 1214:21-1215:1 ("Are you aware of the phrase 'due diligence' being in either the statute or the regulation? … THE WITNESS: It's not."); Ashley Tr. 214:21-216:4 ("Q. Do you know if due diligence is codified anywhere? A. No. …").

regulation or in the CSA that a distributor must conduct any further "due diligence" or investigation of the customer or shipment.[54]

47. This is because it is DEA's responsibility to police the closed loop system of distribution.[55] DEA has the enforcement powers over the closed loop system, not registrants.[56] DEA conducts diligence on applicants for controlled substances registrations.[57] Under the CSA, the closed loop system allows distributors to rely on DEA's approval of the registrations when complying with § 1301.74(a).[58]

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[54] 21 C.F.R. § 1301.74(a); Rafalski Tr. (May 13, 2019) at 386:18-387:4 ("Q. It's true that distributors are to rely on active DEA registrations when complying with 1301.74(a)? A. Yes, sir. They are required by regulation to make a good-faith effort to confirm that the person that they're going to distribute drugs to has a valid DEA registration. Q. And that's actually the only requirement under Section 1301.74(a), correct? A. Yes, it is."); Rannazzisi Tr. (May 15, 2019) at 534:4-9 ("Q. Okay. Now, in that section, does the word or words 'know your customer' appear? A. No, ma'am. Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am."); Ashley Tr. at 214:21-216:4 ("Q. Do you know if due diligence is codified anywhere? A. No. …"); Prevoznik Tr. (May 17, 2019) at 1214:21-1215:1 ("Q. Are you aware of the phrase 'due diligence' being in either the statute or the regulation? … A. It's not.").

[55] Rafalski Tr. (May 13, 2019) at 346:4-13 ("Q. But you agree that DEA is the agency in the federal government that has authority and responsibility for the controlled system of drug distribution in this country, correct? A. In -- yes, sir. In regards to the regulation, they're delegated that by the Attorney General, by Congress to the Attorney General, so I agree with that statement, yes, sir."); Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68 ("[I]n the case of the most potentially dangerous drugs, in Schedule II, we register all persons who handle them; we inspect the documentation of their distribution; we control their import and export; and we control the amount produced, bought, sold, and otherwise transferred."), *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[56] Rannazzisi Tr. (May 15, 2019) at 589:20-590:4 ("Q. Now, the immediate suspension order is an enforcement power possessed by DEA, correct? A. It's an administrative enforcement tool. Q. And -- and an immediate suspension order is a process by which DEA immediately suspends or revokes a registrant's controlled substance license, correct? A. Yes.").

[57] Rafalski Tr. (May 13, 2019) at 385:23-386:4 ("Q. You'd agree with me that DEA conducts diligence on its applicants so that distributors can rely on the DEA registrations when complying with 1301.74(a)? A. Whether or not they posses [sic] a valid DEA registration, is that what you're asking? Yes, sir.").

[58] Rafalski Tr. (May 13, 2019) at 385:23-386:4 ("Q. You'd agree with me that DEA conducts diligence on its applicants so that distributors can rely on the DEA registrations when complying with 1301.74(a)? A. Whether or not they posses [sic] a valid DEA registration, is that what

**h) Section 1301.74(b) requires a suspicious order monitoring program and the reporting of suspicious orders "when discovered"**

48. Section 1301.74(b) states that a registrant must "design and operate" a system that identifies "suspicious orders of controlled substances."[59] The regulation also states that a registrant "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."[60] Subsection (b) of the regulation describes the requirement to design a suspicious order monitoring program and report "suspicious orders" as follows: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."[61]

49. Section 1301.74(b) leaves the design of the suspicious order monitoring program to the discretion of the distributor.[62] DEA recognizes that there is more than one way that a distributor can design and operate an effective suspicious order monitoring program.[63] Under

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you're asking? Yes, sir."); Diversion Investigators Manual § 5126, 4/16/1996 (CAH_MDL2804_02203353 at -3356) ("DEA field offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship controlled substances.").

[59] 21 C.F.R. § 1301.74(b).

[60] 21 C.F.R. § 1301.74(b).

[61] 21 C.F.R. § 1301.74(b).

[62] 21 C.F.R. § 1301.74(b); Ashley Tr. at 89:13-22 ("Q. And is it correct that the distributors must define their own parameters for a suspicious order? A. There's some regulation requirement that it be effective. So other than that, it's their discretion, but it just must be effective. Q. And whether a system is effective is in itself a subjective determination; isn't that correct? A. Yes, I would agree with that.").

[63] Prevoznik Tr. (Apr. 17, 2019) at 179:22-180:2 ("Q. Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A. Yes.").

the CSA and the regulations, DEA leaves it to the discretion of the distributor to design a controlled substance monitoring system that works for the distributor's business and customer base.[64] DEA has emphasized that there is no single feature that makes a suspicious order monitoring program compliant with § 1301.74(b).[65] DEA even lacked an internal guidance explaining what type of suspicious order monitoring program complied with the regulations.[66]

**i) Sections 1301.74(c)-(m) Impose Additional Security Requirements**

50. Section 1301.74(c), like § 1301.76(b), requires non-practitioner registrants to disclose theft or loss of controlled substances to the relevant DEA Field Division Office within one business day of discovery of such theft or loss.[67] The security requirements set out in the regulations also cover transportation of controlled substances. Section 1301.74(e) states that "a

[64] Prevoznik Tr. (Apr. 17, 2019) at 180:7-11 ("Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct."); Rannazzisi Tr. (Apr. 26, 2019) at 321:8-21 ("Q. So how does a registrant know that their system is enough that it is compliant with the regulations?... A. Because the regs tell them that they must design and operate a system that identifies suspicious orders and they have to report. How they create that system is a business decision and as long as it identifies and reports suspicious orders, then -- and they are comfortable with that system, then they have a system."); Rannazzisi Tr. (Apr. 26, 2019) at 321:23-322:9 ("Q. So there is more than one way to design a compliant suspicious order monitoring system? … THE WITNESS: I don't -- I don't know what the different ways of creating a system is. Again, I can only go by what the regulation says and it is up to the registrant to design and operate a system.").

[65] Prevoznik Tr. (Apr. 17, 2019) at 180:3-6 ("Q. And there's no single feature that makes a suspicious order monitoring system compliant, correct? A. Correct."); Ashley Tr. at 88:2-10 ("Q. To your knowledge, is there a particular formula or algorithm that is required for a legally compliant system? … A. To my knowledge, there is not.").

[66] Rannazzisi Tr. (Apr. 26, 2019) at 317:24-318:7 ("Q. In the time period 2005 to 2016, yes or no, did DEA have internal guidance as to what constituted a suspicious order monitoring system that complied with regulations? … THE WITNESS: I don't know about 2016, but for 2005 to 2015, no.").

[67] 21 C.F.R. § 1301.74(c).

registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses."[68]

**4. Record Retention Requirement under 21 CFR 1304.04**

51. The document retention requirements for registrants are found at 21 CFR § 1304.04. Section 1304.04 requires that registrants keep "inventory and other records" for "at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration."[69] There is no requirement in the CSA or federal regulations that registrants keep "inventory or other records" for longer than two years.[70] In addition, there is no specific requirement in the federal regulation that "due diligence" files or suspicious order reports need to be maintained at all.[71] The recordkeeping of due diligence files is entirely left to the discretion of the distributor.[72]

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[68] 21 C.F.R. § 1301.74(e).

[69] 21 C.F.R. § 1304.04(a); Prevoznik Tr. (May 17, 2019) at 1218:17-23 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant.").

[70] Prevoznik Tr. (May 17, 2019) at 1218:17-23 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant.").

[71] 21 C.F.R. § 1304.04; Prevoznik Tr. (May 17, 2019) at 1216:8-12 ("Q. Coming back to the concept of due diligence, the DEA has not issued any guidance specifying how long a registrant must hold on to due diligence, correct? A. Correct.").

[72] Ashley Tr. at 252:5-18 ("Q. Let's start with that. Is how the records are kept in connection with a suspicious order something that's left to the discretion of distributors just as the decision as to whether an order is suspicious or whether an order should be shipped? A. How the records are kept are left to the discretion of the distributor, yes. Q. Is the documentation of a distributor suspicious order monitoring system how it's -- how it is set up and how it's implemented also something that is in the discretion of the distributors? A. Yes."); Ashley Tr. at 254:1-5 ("Q. Yes, ma'am. Is how a distributor documents the due diligence it conducts something that's in the discretion of the distributor? A. How they document it? How they do it, I'd have to say, yes."); Wright Tr. (Feb. 28, 2019) at 143:2-12 (Q. Okay. And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a

### C. The Requirements Not Imposed by the CSA and the Regulations

52. DEA's guidance to distributors shifted beginning with the Distributor Initiative, but the requirements of the CSA and its regulations for distributors have not changed.[73] In addition, the requirements not included in the CSA and its regulations have remained the same. The CSA and its regulations do not require a registrant to "know your customer" or conduct due diligence other than the "good faith inquiry" described in § 1301.74(a) to retain records indefinitely, or to block suspicious orders.

#### 1. The CSA and Regulations Do Not Contain Due Diligence & "Know Your Customer" Requirements Other Than the Good Faith Inquiry Described in § 1301.74(a)

53. The CSA and its regulations do not require distributors or other registrants to "Know Your Customer" or to conduct due diligence beyond the requirement in § 1301.74(a) that a registrant make a good faith inquiry to make sure that its customers who receive controlled substances hold proper registrations.[74] Section 1301.74(b) does not require registrants to investigate or perform "due diligence" on an order that meets the regulation's definition of a

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suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? … A. No."); Wright Tr. (Mar. 4, 2019) at 496:23-497:10 ("Q. And it is the documentation of -- whatever due diligence is done by a company, that may be a best practice, but it is not required by statute or regulation, correct. … A. Yes, ma'am. … Q. When you did your distributor briefings, you did not note in your distributor briefings the documentation of due diligence did you? A. No, ma'am.").

[73] Rannazzisi Tr. (Apr. 26, 2019) at 68:1-14, 253:19-23; Wright Tr. (Feb. 28, 2019) at 125:20-126:11.

[74] 21 U.S.C. § 823; 21 C.F.R. § 1301.74; Prevoznik Tr. (Apr. 17, 2019) at 216:16-217:18 ("Q. And there's no requirement for distributors and manufacturers to document their "know your customer" process, correct? … THE WITNESS: There's not a written – written requirement – regulation or requirement of that. However, if you're going to maintain effective control for diversion, you're going to have to be able – you're going to have to be able to explain how you made that assessment. Was this – especially in terms of suspicious orders, how you came to the conclusion that this was not a suspicious order. So … Q. Is there a best practice document that was distributed to distributors and manufacturers that says that? … THE WITNESS: No.").

"suspicious order."[75] In fact, the terms "due diligence" and "Know Your Customer" are not found in § 1301.74.[76] In addition, a registrant is not required under the regulation to determine if an order that meets the definition of "suspicious order" under the regulation is actually going to be diverted or is actually "suspicious" as that term is commonly used.

### 2. The CSA and Its Regulations Contain Limited Record Retention Requirements

54. The record retention requirements provided in the CSA and its regulations are limited.[77] The CSA's record retention requirement is limited to only two years for "inventory or other record[s]."[78] The CSA does not contain language requiring the retention of suspicious order reports or due diligence files.[79] The regulations issued under the CSA also only require distributors to retain "inventory and other records" for two years.[80] Section 1304.04 does not

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[75] Wright Tr. (Mar. 4, 2019) at 496:8-14 ("Q. So the due diligence that got referenced in your discussion this morning, that is not required by the statute or the regulation, correct? ... A. It is not mentioned specifically.").

[76] 21 C.F.R. § 1301.74(b); Rannazzisi Tr. (May 15, 2019) at 526:19-527:3 ("Q. Okay. Now, within the Controlled Substances Act, and in particular those -- those subparagraphs the words 'know your customer' does not appear, correct? A. The words 'know your customer' is not in the Controlled Substances Act. Q. And the words 'due diligence' are not in the Controlled Substances Act either, right? A. That is correct."); Prevoznik Tr. (May 17, 2019) at 1214:21-1215:1 ("Are you aware of the phrase 'due diligence' being in either the statute or the regulation? … THE WITNESS: It's not."); Wright Tr. (Mar. 4, 2019) at 496:8-14 ("Q. So the due diligence that got referenced in your discussion this morning, that is not required by the statute or the regulation, correct? … THE WITNESS: It is not mentioned specifically.").

[77] Prevoznik Tr. (May 17, 2019) at 1218:17-23 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant.").

[78] 21 U.S.C. § 827(b).

[79] 21 U.S.C. § 827.

[80] 21 C.F.R. § 1304.04(a); Prevoznik Tr. (May 17, 2019) at 1218:17-1219:10 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant. … Q. But there's no requirement that a due diligence file even be maintained, correct? A. Correct. Q. So the two-year rule does not apply to any due

require distributors to retain suspicious order reports or due diligence files for more than two years.[81] DEA left decisions concerning recordkeeping of due diligence and the maintenance of those records to the discretion of the distributor.[82]

### 3. The CSA and Its Regulations Do Not Include a Requirement That Distributors "Do Not Ship"

55. The CSA and the applicable regulations do not require registrants to "block" orders that meet the definition of "suspicious orders."[83] The CSA does not include any requirement that distributors "do not ship" an order that meets the regulatory definition of a suspicious order.[84] Similarly, § 1301.74 says nothing about not shipping a "suspicious order,"

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diligence files, per se, correct? A. Correct. I was just pointing out that within the regs, there is records for a two-year period."); Rannazzisi Tr. (May 15, 2019) at 555:7-11 ("Q. Is there any requirement in the DEA regulations or guidance to maintain due diligence documentation for a certain period of time? A. There's no requirements.").

[81] 21 C.F.R. § 1304.04.

[82] Ashley Tr. at 254:1-5 ("Q. Yes ma'am. Is how a distributor documents the due diligence it conducts something that's in the discretion of the distributor? A. How they document it? How they do it, I'd have to say, yes."); Wright Tr. (Feb. 28, 2019) at 143:2-12 ("Q. Okay. And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? … A. No."); Wright Tr. (Mar. 4, 2019) at 496:23-497:4 ("Q. And it is the documentation of -- whatever due diligence is done by a company, that may be a best practice, but it is not required by statute or regulation, correct? … A. Yes, ma'am.").

[83] 21 C.F.R. § 1301.74(b); Rannazzisi Tr. (May 15, 2019) at 534:19-21 ("Q. Do the words 'do not ship' appear in this regulation [21 C.F.R. § 1301.74(b)]? A. No, ma'am."); Ashley Tr. at 251:17-21 ("Q. You testified earlier today that it was in the discretion of distributors to make the decision whether an order was suspicious and whether to ship, correct? A. Yes."); Rafalski Tr. (May 13, 2019) at 134:25-135:7 ("Q. Does the regulation say anything about ship -- does the regulation in words, words, say anything about shipping? … A. It does not say the word 'shipping.'").

[84] Ashley Tr. at 242:12-19 ("Q. And your personal understanding was what? A. That we do not tell registrants that they cannot ship an order, especially solely on a suspicious order report and no other information. Q. Because I think as you told Ms. Zolner a few minutes ago, the decision to ship or not ship is solely in the discretion of the distributor? A. Yes."); Prevoznik Tr. (Apr. 17, 2019) at 167:5-12 ("Q. Did the Controlled Substances Act contain any language that states

and the words "block" and "do not ship" are nowhere in the regulation.[85] There is also nothing in § 1301.74 that requires a distributor to "block" or "do not ship" an order meeting § 1301.74(b)'s definition of a "suspicious order."[86]

#### 4. The CSA and Its Regulations Do Not Define "Orders of Unusual Size," "Orders Deviating from a Normal Pattern," and "Orders of Unusual Frequency"

56. "[S]uspicious orders" are defined in § 1301.74(b) as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[87] Section 1301.74, however, does not define or explain the terms used in the definition of suspicious order.[88] The regulation does not define or explain what DEA means by "unusual size," "deviating substantially from a normal pattern," or "unusual frequency."[89] In guidance letter to distributors, DEA said the size, frequency, and pattern are "disjunctive and not all

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whether or not a distributor could ship a suspicious order? A. It doesn't say specifically that. It does say that it needs to be -- it has to maintain -- maintain effective control against diversion.").

[85] 21 C.F.R. §1301.74(b); Rannazzisi Tr. (May 15, 2019) at 534:19-21 ("Q. Do the words 'do not ship' appear in this regulation [21 C.F.R. § 1301.74(b)]? A. No, ma'am."); Rafalski Tr. (May 13, 2019) at 349:22-350:8 ("Q. But you agree with me that the security requirement [1301.74(b)] itself does not say the words 'do not ship,' does it? A. The security requirements do not say those specific three words. Q. And the security requirement does not say 'block orders,' does it? A. It doesn't -- the security requirement doesn't specifically say that….").

[86] Ashley Tr. at 242:12-15 ("Q. And your personal understanding was what? A. That we do not tell registrants that they cannot ship an order, especially solely on a suspicious order report and no other information.").

[87] 21 C.F.R. § 1301.74(b).

[88] 21 C.F.R. § 1301.74.

[89] 21 C.F.R. § 1301.74; Ashley Tr. at 26:16-22 ("Q. Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A. No. Q. Does the regulation provide guidance as to what constitutes an order of unusual frequency? A. No."); Ashley Tr. at 147:8-11 ("Q. Based on your experience, would you agree that there might be situations where an order is of an unusual size, but the order is not suspicious? A. Yes.").

inclusive."[90] Even witnesses who have testified in this litigation for DEA have been unable to define a "suspicious order" in a consistent way.[91]

57. The lack of consensus among DEA witnesses is not surprising because the meanings of "unusual size," "unusual frequency," and "order deviating substantially from a normal pattern" are subjective.[92] The meaning of each term will change depending on customers, the registrant, and the orders at issue.[93] DEA left it to a distributor's discretion to

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[90] December 27, 2007 Dear Registrant Letter (MCKMDL00478910 at -8910).

[91] Rafalski Tr. (May 13, 2019) at 57:17-21 ("A. I think the regulation itself [1301.74, subpart (b)] is a broad regulation … I think the actual full definition is up to the registrant, depending on a lot of factors; the scope of their business and the scope of those customers that receive products from them."); Rafalski Tr. (May 13, 2019) at 58:5-16 ("Q. The regulation defines suspicious orders as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency; is that correct? A. Well, that is what the regulation says, but -- I'm not so sure I agree if you're saying the word 'defines' says that suspicious orders could only be those things. I think that's up to the registrant …."); Rannazzisi Tr. (Apr. 26, 2019) at 57:15-23 ("I think that the suspicious order monitoring regulation 1301.74(b) was -- the definition of suspicious order is very straightforward. I don't know what other information I could provide to them to clarify what a suspicious orders [sic] is without making a business decision for them, which the regulations would not allow me to do."); Rannazzisi Tr. (Apr. 26, 2019) at 119:21-120:4 ("DEA doesn't -- DEA does not tell a registrant or either the man -- or a registrant involved in distribution activities what's a suspicious order, besides the -- the definition in 1301.74(b). It's up to the -- the distributor or the manufacturer, distributor to make a decision what information they will use to determine a suspicious orders [sic].").

Additionally, these witnesses were not the ones who told registrants what was expected of them under 1301.74(b); Rannazzisi Tr. (Apr. 26, 2019) at 267:20-268:3 ("I don't -- I haven't had the opportunity -- well, I have never told a registrant what their responsibility is as far as what my definition of a suspicious order is. That would have come from my staff or the liaison policy section or the pharmaceutical investigation section or E-commerce, you know, if they were still there, but it wouldn't have come from my office directly."). The witnesses were not able to say for sure that their definitions of unusual size, etc., were the same as what their staff would have told registrants. Rannazzisi Tr. (Apr. 26, 2019) at 279:8-18 ("Q. Sitting here today, you can't tell me that your definition of unusual size is the same as Michael Mapes's definition of unusual size, right? … A. I don't know what Mr. Mapes's definition of unusual size is.").

[92] Ashley Tr. at 26:1-8 ("Q. If you look at Section B of this regulation, does the regulation tell registrants, specifically distributors, how to identify suspicious orders? A. I guess my answer would be somewhat, yes. Q. Okay. Is there an element of subjectivity to it? A. Yes.")

[93] Ashley Tr. at 26:23-27:13 ("Q. Does the regulation provide guidance as to what constitutes an order that deviates substantially from normal ordering pattern? A. I would have to say in general, yeah, it does. Q. How does it do that? A. By saying it's deviating from the normal

define the parameters of a suspicious order.[94] DEA believed it was up to the registrant to determine what was "an order of unusual size," an order of "unusual frequency," and an order that deviated "substantially from a normal pattern."[95] Furthermore, DEA has acknowledged that even if an order meets the definition of a "suspicious order," the order is not necessarily suspicious.[96]

### 5. The CSA and Its Regulations Do Not Restrict a Distributor's Discretion to Establish Its Suspicious Order Monitoring Program

58. Section 1301.74(b) and the CSA do not provide specific guidance about what a compliant suspicious order monitoring program looks like.[97] The lack of detail in § 1301.74(b) is notable because DEA provided many detailed requirements when it set out the requirements for physical security in the regulations. DEA left the design of the suspicious order monitoring program to the discretion of the registrant.[98]

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pattern. Q. Okay. And does it explain what that means? A. You would need to know what was normal, so I think so. Q. And would normal vary from case to case? A. Yes. Q. And situation to situation? A. Yes.").

[94] Ashley Tr. at 89:13-22 ("Q. And is it correct that the distributors must define their own parameters for a suspicious order? A. There's some regulation requirement that it be effective. So other than that, it's their discretion, but it just must be effective. Q. And whether a system is effective is in itself a subjective determination; isn't that correct? A. Yes, I would agree with that.").

[95] Ashley Tr. at 26:16-22 ("Q. Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A. No. Q. Does the regulation provide guidance as to what constitutes an order of unusual frequency? A. No.").

[96] Ashley Tr. at 147:8-11 ("Q. Based on your experience, would you agree that there might be situations where an order is of unusual size, but the order is not suspicious? A. Yes.").

[97] Prevoznik Tr. (Apr. 17, 2019) at 180:3-11 ("Q. And there's no single feature that makes a suspicious order monitoring system compliant, correct? A. Correct. Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct.").

[98] Rannazzisi Tr. (Apr. 26, 2019) at 321:8-322:9 ("Q. So how does a registrant know that their system is enough that its compliant with the regulations? … THE WITNESS: Because the regs tell them that they must design and operate a system that identifies suspicious orders and they

59. DEA left it to the registrant to determine what a suspicious order looked like and how to monitor and report such orders, and DEA acknowledged there was more than one way for a distributor to design a suspicious order monitoring system. [99] DEA employee Kyle Wright confirmed this in testimony from 2011:

> Q: So DEA was not going to tell the registrant community, "You're doing it right," or, "You're not doing it right"?
>
> A: That's right. It's not our business. . . .
>
> I will put forth on this table right now that there is a lot of unanswered and ambiguity that exists with the industry and that also exists with DEA. . . . And it has remained ambiguous, because what DEA did is they turned the full [a]mount of responsibility on the registrant community.[100]

60. Mr. Rannazzisi, for example, testified that "it is up to the registrant to design and operate a system."[101]

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have to report. How they create that system is a business decision and as long as it identifies and reports suspicious orders, then -- and they are comfortable with that system, then they have a system. … Q. So there is more than one way to design a compliant suspicious order monitoring system? … THE WITNESS: I don't -- I don't know what the different ways of creating a system is. Again, I can only go by what the regulation says and it is up to the registrant to design and operate a system."); Prevoznik Tr. (Apr. 17, 2019) at 180:3-11 ("Q. And there's no single feature that makes a suspicious order monitoring system compliant, correct? A. Correct. Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct.").

[99] Prevoznik Tr. (Apr. 17, 2019) at 179:22-180:2 ("Q. Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A. Yes.").

[100] Wright Tr. (US v. $463,497.72) at 43:22-25, 54:16-24.

[101] Rannazzisi Tr. (Apr. 26, 2019) at 322:8-9.

### D. DEA Audits Registrants to Assess Their Regulatory Compliance

61. I conducted and oversaw unannounced audits of manufacturer and distributor sites during my time at DEA. I continue to perform audits of manufacturers and distributors now as a consultant.

62. During my time at DEA, the audits that I conducted and oversaw primarily focused on determining whether the registrant complied with key requirements of the CSA and its regulations.[102] The audits covered three areas: physical security, recordkeeping, and accountability.[103] This included whether a registrant's policies and procedures met physical security standards and complied with ARCOS reporting requirements.[104] After 2006, we were

[102] Rafalski Tr. (May 13, 2019) at 343:3-22 ("Q. And that's fair, but it's one of the purposes of this audit for DEA to go to the facility of the distributor to review the SOM system and to provide feedback, correction -- corrective feedback to the distributor, if corrective feedback is needed? A. So can I describe a little bit further what an on-site visit is? It's not a checklist type of a visit. It's a three-pronged investigation: security, recordkeeping and accountability. Every DEA investigator conducts it in whatever manner they see fit as long as they cover those three areas or prongs of activity. So it's -- there's nothing in the DEA's requirement that they would specifically have to look at that or take action, although I would say my expectation is they should.").

[103] Rafalski Tr. (May 13, 2019) at 343:10-14 ("A. So can I describe a little bit further what an on-site visit is? It's not a checklist type of a visit. It's a three-pronged investigation: security, recordkeeping and accountability."); Blaine Snider ("Snider") Tr. (Nov. 8, 2018) at 458:20-24 ("So when the DEA or we do our audits, we check our licensing and numerous other things, but the DEA has been in there a few times, and they've always had exemplary comments for New Castle and our team."); Michael Oriente ("Oriente") Tr. (July 25, 2018) at 579:4-17 ("Q. Could you describe the relationship you've had with the DEA over the course of your career in McKesson regulatory affairs? A. Yes. I felt that my relationship with DEA was very good. When I started in '07 in regulatory, our Delran distribution center was always one where the DEA paid compliments to when they came in to do their cyclical audits. Our recordkeeping was always good. Our inventory was good. So the local DEA office over my distribution center was always satisfied with what we were doing.").

[104] Rafalski Tr. (May 13, 2019) at 343:10-22 ("A. So can I describe a little bit further what an on-site visit is? It's not a checklist type of a visit. It's a three-pronged investigation: security, recordkeeping and accountability. Every DEA investigator conducts it in whatever manner they see fit as long as they cover those three areas or prongs of activity. So it's -- there's nothing in the DEA's requirement that they would specifically have to look at [the SOM system] or take action, although I would say my expectation is they should."); Prevoznik Tr. (Apr. 17, 2019) at

advised and trained to examine a registrant's suspicious order reporting procedures as part of a broader review of the registrant's suspicious order monitoring programs. DEA employee Thomas Prevoznik confirmed that DEA would review suspicious order monitoring systems as part of the audit process.[105]

63. During the audit process, we would walk through a site and note potential concerns.[106] Following a DEA audit, if I or others identified flaws or concerns, we would inform the registrant so it could take remedial action.[107] However, we would not provide feedback if an

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130:13-131:14 ("Q. So as part of the audit process, operating systems that are designed to review suspicious orders are reviewed by the DEA? A. … So it comes in -- it comes in various times that we're going to review somebody's operating system, whether we're on schedule investigation, or whether we're doing an investigation on a pharmacy or something like that, where we're going to look at how many SORs were submitted or not submitted, or we're going to look at the ARCOS data, how much did they buy. We're going to look at various things to make the determination on what is going on.").

[105] Prevoznik Tr. (Apr. 17, 2019) at 130:13-131:14 ("Q. So as part of the audit process, operating systems that are designed to review suspicious orders are reviewed by the DEA? A. … So it comes in -- it comes in various times that we're going to review somebody's operating system, whether we're on schedule investigation, or whether we're doing an investigation on a pharmacy or something like that, where we're going to look at how many SORs were submitted or not submitted, or we're going to look at the ARCOS data, how much did they buy. We're going to look at various things to make the determination on what is going on.").

[106] Prevoznik Tr. (Apr. 17, 2019) at 131:15-23 ("Q. And if either in the pre-registration process or in the audit process the DEA determines that a registrant's system is not adequately detecting suspicious orders, is that something that is conveyed to the registrant? A. Yeah, we -- we would tell them, you need to add something."); Rafalski Tr. (May 13, 2019) at 342:9-21 ("Q. So if McKesson's Section 55 program had been out of compliance with federal regulations and DEA was conducting audits of the McKesson facilities, wouldn't DEA have told McKesson during its annual audits that its program was out of compliance? A. I would have an expectation that if a person was to go on site and actually review the system, that I would have an expectation that there -- maybe should make some comment or do some corrective action.").

[107] Prevoznik Tr. (Apr. 17, 2019) at 131:15-23 ("Q. And if either in the pre-registration process or in the audit process the DEA determines that a registrant's system is not adequately detecting suspicious orders, is that something that is conveyed to the registrant? A. Yeah, we -- we would tell them, you need to add something."); Rafalski Tr. (May 13, 2019) at 342:9-21 ("Q. So if McKesson's Section 55 program had been out of compliance with federal regulations and DEA was conducting audits of the McKesson facilities, wouldn't DEA have told McKesson during its annual audits that its program was out of compliance? A. I would have an expectation that if a

audit did not identify any flaws, and a registrant performed well. It was DEA's practice to not provide any written documentation, reports, or feedback to indicate that the registrant had successfully passed an audit.

64. DEA audited McKesson a number of times before 2006 when McKesson's Section 55 suspicious order monitoring program was in use.[108] Donald Walker, the former Vice President of Regulatory Affairs at McKesson, stated that during that time DEA did not inform McKesson that McKesson's Section 55 program was not compliant with the requirements in the CSA and its regulations.[109] Based on my experience as a diversion investigator, McKesson would have been told if DEA found that McKesson's Section 55 program did not comply with the CSA and regulations.[110] The lack of any report that Section 55 was not compliant is

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person was to go on site and actually review the system, that I would have an expectation that there -- maybe should make some comment or do some corrective action.").

[108] Snider Tr. (Nov. 8, 2018) at 183:11-13 ("If I could answer that, the DEA has done audits on us. We've never been found to do anything wrong."); Snider Tr. (Nov. 8, 2018) at 458:4-19 ("Q. Okay. And the next -- the other audit you were going to describe? A. Yes. Sorry. The next audit is the DEA cyclic audit or any DEA unannounced audit. So we've had cyclic audits average two-and-a-half years. They try to do them every two years, but -- so I believe there were four audits at the distribution center by the DEA, and they've all came out as -- a hundred percent as exemplary. So that was one of the other audits. And then monthly, we did the triannual report, which was a DEA SOPs. And then also we did a VAWD audit, which is the National Wholesale Association. We do that every two to five years depending on our licensure. We were one of the first DCs to get VAWD accreditation."); Donald Walker ("Walker") Tr. (Jan. 10, 2019) at 406:1-9 ("Additionally, the DEA continued to conduct their cyclical audit. A cyclical audit is where the DEA comes in unannounced and inspects the distribution center in a number of different areas, primarily around the recordkeeping, the security of the controlled substances, the handling, reviewing the associates that are authorized to handle controlled substances. All of that is part of the normal cyclical audit.").

[109] Walker Tr. (Jan. 10, 2019) at 406:10-20 ("Q. And what would happen if DEA found an issue during one of those cyclical audits? A. Excuse me. There was an Audit Report that was generated out of each one of the audits. If there were actions that needed to be taken by McKesson to correct anything that they identified in the audit, virtually all the time that I can recall, those were fairly minor issues. They were more what I would call procedural. We made the procedural adjustments and reported back to DEA the changes that we made.").

[110] Rafalski Tr. (May 13, 2019) at 342:9-21 ("Q. So if McKesson's Section 55 program had been out of compliance with federal regulations and DEA was conducting audits of McKesson

important because it means that McKesson's Section 55 program successfully passed DEA's audits.

65. Based on my experience, it is my opinion that DEA would have informed McKesson during an audit if McKesson's Section 55 program failed to sufficiently detect suspicious orders as required by DEA guidance at the time or if it failed to comply with the CSA and its regulations. My opinion regarding McKesson's Section 55 program passing DEA's audits is confirmed by testimony from DEA employee Thomas Prevoznik, who testified that it was DEA's practice to inform registrants during an audit if their suspicious order monitoring programs failed to adequately detect suspicious orders.[111] In particular, DEA would inform a registrant during the closing meeting with management if the program did not comply with the CSA and its regulations. In addition, DEA employees have also testified that it was reasonable for a registrant to rely on information conveyed to the registrant by DEA during the audit.[112]

### E. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 Did Not Weaken DEA's Enforcement Capabilities

66. The CSA and its regulations relating to suspicious order monitoring programs were not materially changed until the Ensuring Patient Access and Effective Drug Enforcement

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facilities, wouldn't DEA have told McKesson during its annual audits that its program was out of compliance? A. I would have an expectation that if a person was to go on site and actually review the system, that I would have an expectation that there -- maybe should make some comment or do some corrective action.").

[111] Prevoznik Tr. (Apr. 17, 2019) at 131:15-23 ("Q. And if either in the pre-registration process or in the audit process the DEA determines that a registrant's system is not adequately detecting suspicious orders, is that something that is conveyed to the registrant? A. Yeah, we -- we would tell them, you need to add something.").

[112] Prevoznik Tr. (Apr. 18, 2019) at 461:13-21 ("Q. Okay. And the registrants who are visited by DEA field office personnel can rely on the information that they receive from DEA field division personnel regarding SOMs systems, true? … THE WITNESS: Yeah, they get guidance.").

Act of 2016 was enacted.[113] Relevant to this case are the Ensuring Patient Access Act's amendments that relate to immediate suspension orders. The CSA allows DEA to immediately suspend a registration to prevent "imminent danger to the public health or safety."[114] The term "imminent danger to the public health and safety" was not defined in the CSA.[115]

67. The Ensuring Patient Access Act, however, defined the term. "Imminent danger to the public health and safety" is defined in the Ensuring Patient Access Act to mean an immediate threat of death, serious bodily harm, or abuse of a controlled substance due to a registrant's failure to maintain effective controls against diversion.[116] The Ensuring Patient Access Act also requires an order to show cause for denying, revoking or suspending a registration to specifically state the legal basis for the action and notify the registrant of the opportunity to submit a corrective action plan.[117]

68. I understand that Joseph Rannazzisi has criticized the Ensuring Patient Access Act, stating that the Act weakens DEA's ability to enforce the CSA.[118] Joseph Rannazzisi, however, left DEA in 2015. He was not with DEA when the Ensuring Patient Access Act took

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[113] Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub L. No. 114-145, 130 Stat. 354, *available at* https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf.

[114] 21 U.S.C. § 824(d)(1).

[115] 21 U.S.C. § 824(d)(1).

[116] Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub L. No. 114-145, 130 Stat. 354 at 354, *available at* https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf.

[117] Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub L. No. 114-145, 130 Stat. 354 at 354-55, *available at* https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf.

[118] Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph over the DEA*, Washington Post (Oct. 15, 2017), *available at* https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.f373cbcb3255.

effect in 2016.[119] During his deposition, Joseph Rannazzisi testified that the evidence of the Ensuring Patient Access Act negatively affecting DEA's ability to issue Immediate Suspension Orders ("ISOs") is that DEA has not filed an ISO against a manufacturer or distributor since the Act passed three years ago.[120] However, DEA did not file an ISO against a manufacturer or distributor in the four years *before* the Ensuring Patient Access Act took effect.[121] Similarly, the number of immediate suspension orders issued by DEA against pharmacies and practitioners decreased significantly before the Ensuring Patient Access Act was enacted. The number of immediate suspension orders filed against pharmacies decreased from 21 to 4 between 2011 and 2016.[122] The number of immediate suspension orders filed against practitioners decreased from 43 to 5 between 2011 and 2016.[123]

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[119] Rannazzisi Tr. (May 15, 2019) at 515:19-516:5 ("Q. And so the bill that Mr. Lanier asked you about that -- that essentially hampered DEA's ability to control diversion, I think were the word that were used, that was passed in 2016? A. Yes. Q. And that was prior -- you left prior to 2016, correct? A. Yes. Q. So that bill was passed after you left the DEA? A. That is correct.").

[120] Rannazzisi Tr. (May 15, 2019) at 516:6-15 ("Q. So you don't necessarily have any firsthand knowledge of how that bill hampered DEA's ability to control diversion, correct? A. DEA hasn't issued an immediate suspension order that I'm aware of, except for one, which was withdrawn, since the passage of that bill related to manufacturers and distributors. So I believe, yes, that's probably correct.").

[121] Statement of Senator Dianne Feinstein, Senate Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act (Dec. 12, 2017), at 2, *available at* https://www.judiciary.senate.gov/imo/media/doc/Feinstein%20Statement%2012-12-17.pdf.

[122] Statement of Senator Dianne Feinstein, Senate Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act (Dec. 12, 2017), at 2, *available at* https://www.judiciary.senate.gov/imo/media/doc/Feinstein%20Statement%2012-12-17.pdf.

[123] Statement of Senator Dianne Feinstein, Senate Hearing on Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act (Dec. 12, 2017), at 2, *available at* https://www.judiciary.senate.gov/imo/media/doc/Feinstein%20Statement%2012-12-17.pdf.

## VI. What is Diversion?

### A. Definition of Diversion

69. As a police officer and member of the Philadelphia DEA Task Force, DEA Diversion Investigator, and Diversion Group Supervisor at DEA's Philadelphia Field Office, I have a comprehensive understanding of the meaning of diversion, the related statutes and regulations that are intended to prevent diversion, and the many ways diversion occurs. For decades, I was focused on anti-diversion efforts.

70. Diversion is a technical term for when prescription medications are taken out of legitimate channels and used for illegitimate and illegal purposes.[124] When diversion occurs, a controlled substance is removed from the closed loop system of distribution or from legitimate channels (such as patients with valid prescriptions) and moved to illicit channels for abuse.[125] Diversion encompasses a variety of situations, including when (1) someone steals a controlled substance from any entity with appropriate access to that controlled substance; (2) a patient sells a controlled substance originally prescribed to them by a doctor for a legitimate medical purpose; or (3) a doctor writes a prescription for a controlled substance that does not address a legitimate medical need, and the patient, in turn, fills the prescription.

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[124] Gary Boggs ("Boggs") Tr. (Jan. 17, 2019) at 354:6-12 ("Q. Mr. Boggs, I want to ask you some questions about diversion. What is diversion? A. Diversion is the act of taking pharmaceutical controlled substances out of the closed system of distribution or from legitimate channels, patients, and then moving them into -- outside of that for abuse."); Rannazzisi Tr. (May 15, 2019) at 381:23-382:8 ("Q. All right. Now I think everybody is going to know by the time we play your deposition, but just in case they don't, define for U.S. what is diversion. A. Diversion is when pharmaceuticals or listed chemicals are taken from the normal stream or the legitimate stream of commerce and moved into the illicit marketplace. Q. So diversion happens when drugs are diverted from their legal use? A. Basically, yes.").

[125] Boggs Tr. (Jan. 17, 2019) at 354:6-12 ("Q. Mr. Boggs, I want to ask you some questions about diversion. What is diversion? A. Diversion is the act of taking pharmaceutical controlled substances out of the closed system of distribution or from legitimate channels, patients, and then moving them into -- outside of that for abuse.").

71. Diversion is distinct from overprescribing. Overprescribing occurs when well-intentioned prescribers (e.g., doctors, nurses, dentists, etc.) write prescriptions for legitimate medical purposes, but either prescribe too strong of a substance or too much of a substance to meet the medical need. For example, if a well-meaning dentist were to write a prescription for forty tablets of oxycodone 30 mg to a patient with a tooth extraction, that might well be viewed as overprescribing, but it would not be diversion. Where a provider knowingly prescribes opioids or another controlled substance in the absence of medical need, that is diversion. Over the last 30 years, overall prescribing rates for opioids have skyrocketed.[126] Overwhelmingly, this increase is due to overprescribing by the medical community writ large, not to diversion; prescribers who are diverting controlled substances account for a tiny fraction of increased prescribing figures.[127]

**B. Primary Causes of Diversion**

72. Based on my experience at DEA, it is my opinion that the primary causes of diversion have included drug-seeking patients, criminal prescribers who knowingly prescribe to patients in the absence of a legitimate medical need, rogue internet pharmacies, and brick-and-mortar pill mills. Joseph Rannazzisi testified to Congress that the "most common methods of diversion witnessed are through doctor shopping, prescription fraud, improper prescribing and

[126] National Institute on Drug Abuse, America's Addiction to Opioids: Heroin and Prescription Drug Abuse, Figure 1, *available at* https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[127] Expert Report of Anna Lembke (Mar. 25, 2019) at 9-14; Lembke Tr. (Apr. 24, 2019) at 218:13-220:1.

sharing among family and friends."[128] DEA presentations state that the primary focus of DEA diversion investigations are "indiscriminate/illegal prescribing; illegal sales; theft, robbery, burglary; fraudulent prescriptions; and doctor shopping.[129] Mr. Rannazzisi also testified to Congress that "the vast majority of diversion occurs at the retail level, once the product is in the hands of practitioners and patients."[130]

73. Diversion can occur at different levels outside the control of distributors.[131] Mr. Rannazzisi testified that:

> Pharmaceutical investigations and surveys of state and local law enforcement agencies and state medical boards have revealed that the most common methods of controlled substance prescription drug diversion include "doctor shopping" or other prescription fraud, illegal online pharmacies, theft and burglary (from residences, pharmacies, etc.), stereotypical drug dealing (selling pills to others), receiving from friends or family, and negligent or intentional over-prescribing by physicians or other practitioners.[132]

[128] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 59, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[129] DEA/OD 11th Pharmaceutical Industry Conference, Risk Management of Pharmaceutical Controlled Substances (Sept. 16, 2003) (PPLPC030000179742 at -9747).

[130] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[131] Boggs Tr. (Jan. 17, 2019) at 354:18-355:5 ("Q. Well, why can't you prevent all diversion? A. Diversion can occur at different levels outside of the distribution's control. Diversion can occur at a pharmacy by an employee pilfering it. It can occur by a pharmacy being burglarized or robbed. Diversion can occur even after controlled substances have left with a legitimate patient and are sitting in a medicine cabinet of someone's home, and someone steals them out of that medicine cabinet, that's diversion. We certainly can't control that.").

[132] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 63, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

74. Diversion can occur, for example, if an employee illegally steals a controlled substance from a pharmacy.[133] Diversion can also occur if a pharmacy is burglarized or robbed.[134] Diversion also occurs when a friend or family member steals controlled substances from the medicine cabinet of a patient who was legitimately prescribed the medication.[135] Diversion also takes place when someone steals opioids from a friend who was prescribed the opioids for a legitimate medical need.[136] Mr. Rannazzisi further testified before Congress that "preliminary data suggest that the most common method in which controlled substance prescriptions are diverted may be through friends and family."[137]

75. DEA emphasized that "[p]rescription fraud is another common source of diversion."[138] As DEA explained, prescription fraud occurs "whenever prescriptions for controlled substances are obtained under false pretenses, including when prescriptions are forged

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[133] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 63, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[134] Boggs Tr. (Jan. 17, 2019) at 354:20-24 ("A. Diversion can occur at different levels outside of the distributor's control. Diversion can occur at a pharmacy by an employee pilfering it. It can occur by a pharmacy being burglarized or robbed."); Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,722 (Sept. 6, 2006) ("Diversion also occurs at the retail level with thefts from, and robberies of, pharmacies.").

[135] Boggs Tr. (Jan. 17, 2019) at 354:20-355:5 ("A. … Diversion can occur even after controlled substances have left with a legitimate patient and are sitting in a medicine cabinet of someone's home, and someone steals them out of that medicine cabinet, that's diversion. We certainly can't control that."); Rannazzisi Tr. (Apr. 26, 2019) at 53:16-20 ("Q. Someone can go into their grandmother's cabinet, take the grandmother's opioids that she got for a legitimate reason; and that's diversion, isn't it? A. Technically, yes, that's diversion.").

[136] Rannazzisi Tr. (Apr. 26, 2019) at 53:21-24 ("Q. Someone could take opioids from a friend who got them for a legitimate reason. That's diversion. A. Yes.").

[137] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 65, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[138] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,722 (Sept. 6, 2006).

or altered, or when someone falsely claiming to be a physician calls in the prescription to a pharmacy."[139]

76. DEA also stated that "'[d]octor shopping' is another traditional method by which diversion occurs."[140] DEA explained that "doctor shopping" occurs when "[s]ome drug abusers visit multiple physicians' offices and falsely present complaints in order to obtain controlled substances."[141] Mr. Rannazzisi testified to Congress that "'[d]octor shopping' by drug addicts is one of the most common ways that addicts get illegal controlled substances."[142]

77. Generally, pharmacies—which, like distributors, are DEA registrants—work to make sure they are not filling prescriptions for patients who are likely to divert controlled substances or for "rogue" prescribers who prescribe them without a legitimate medical purpose. DEA estimates that rogue prescribers, who are knowingly prescribing controlled substances in the absence of legitimate medical need, amount to about one half of one percent of practitioners.[143]

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[139] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,722 (Sept. 6, 2006).

[140] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,722 (Sept. 6, 2006).

[141] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,722 (Sept. 6, 2006).

[142] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 64, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[143] Prevoznik Tr., Ex. 14, Apr. 17, 2019 (DEA Deputy Administrator Rannazzisi's testimony before the House of Representatives Committee on Energy and Commerce, April 29, 2014) ("I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing.")). During Mr. Rannazzisi's deposition, he confirmed that he made that statement during the April 2014 hearing, and that one half of one percent of doctors were drawing DEA's focus as "rogue doctors." Rannazzisi Tr., 192:5-19, 193:2-9.

### C. The Vast Majority of Orders Meeting the Regulatory Definition of "Suspicious Orders" Are Legitimate and Not Likely to be Diverted

78. It is important to understand that an order that meets the definition of "suspicious order" in § 1301.74(b) is not necessarily likely to be diverted.[144] This is because there are completely legitimate reasons that an order may be found to be of unusual size, unusual frequency, or deviating from the normal pattern.[145] In fact, the vast majority of orders that are of

[144] Prevoznik Tr. (Apr. 17, 2019) at 309:4-6 ("Q. Not every suspicious order leads to diversion, correct? A. Correct."); Prevoznik Tr. (May 17, 2019) at 1206:6-10 ("Q. Now, not every order of unusual size is indicative of diversion, correct? … THE WITNESS: Correct."); Prevoznik Tr. (May 17, 2019) at 1207:11-16 ("Q. And, Mr. Prevoznik, not every order of unusual frequency is indicative of diversion, correct? … THE WITNESS: Correct."); Prevoznik Tr. (May 17, 2019) at 1208:21-1209:2 ("Q. Now, Mr. Prevoznik, not every order that deviates substantially from a normal ordering pattern is indicative of diversion, correct? … THE WITNESS: Correct."); Boggs Tr. (Jan. 17, 2019) at 97:14-98:2 ("Q. I understand that there are all sorts of possibilities, but the fact of the matter is that suspicious orders can lead you to a suspicious customer, true? … THE WITNESS: Without knowing more about the customer, no. … Q. Well -- A. There is an assumption that a suspicious order equals a suspicious customer, and that's very misplaced from my experience."); Boggs Tr. (Jan. 17, 2019) at 363:2-12 ("Q. Well, if the orders are suspicious orders, why doesn't that make the customers suspicious? A. I think that suspicion in this particular context is not the type of suspicion that -- in the way you and I might use the context of suspicious. That's the term under the regulation as to what it's called. But the order is simply identified as an order of unusual size, an order that deviates substantially from a normal pattern or unusual frequency."); Ashley Tr. at 147:8-11 ("Q. Based on your experience, would you agree that there might be situations where an order is of an unusual size, but the order is not suspicious? A. Yes."); Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. You'd agree that not reporting the suspicious order to DEA is not what causes diversion? A. That's correct.").

[145] Prevoznik Tr. (May 17, 2019) at 1206:12-1207:9 ("Q. There could be legitimate reasons for a pharmacy to place an order of unusual size, correct? … THE WITNESS: Correct. … It could be a new hospital opened, a new clinic opened. A new hospice center could have opened. Any one of those."); Prevoznik Tr. (May 17, 2019) at 1207:18-23 ("Q. There could be legitimate reasons for an order of unusual frequency, true? … THE WITNESS: True."); Prevoznik Tr. (May 17, 2019) at 1209:4-7 ("Q. And could there be legitimate reasons for an ordering pattern that is abnormal in some manner? A. Yeah, there could be."); Ashley Tr. at 147:8-148:11; Boggs Tr. (Jan. 17, 2019) at 363:19-364:6 ("Q. So can you give me an example of how a legitimate pharmacy might place an order that you would flag as suspicious, and yet not consider to be suspicious in the lay sense? A. You could have an order come in, they're -- someone didn't put the correct amount that they wanted. They fat fingered a number in there and made a -- made an error, and they're trying to order actually more than what they really intended to. But because that order was placed with us, that would be deemed as an order of unusual size and reported as suspicious.").

unusual size, unusual frequency, or deviating from a normal pattern, at least for a time, but the orders are for legitimate reasons. They may be considered "unusual" as compared to some metric of past orders, which would make them "suspicious" as defined in the regulation, but that does not mean they are indicative of diversion.

79. In pharmacy ordering, significant variation is the norm.[146] Pharmacies order a wide range of products every day in an effort to anticipate future patient needs. For any given product or base code, the daily ordering trends will be extremely volatile, potentially ranging from zero dosage units one day to thousands of dosage units the next, and back to zero again for the next several days or more. For this reason, wholesale distributors often track customer orders by monthly totals rather than by individual order. Monthly totals are less volatile than daily totals, but even on a monthly basis pharmacy ordering habits will vary substantially.[147] A given pharmacy might order many thousands more dosage units of a particular base code one month than in the previous month, or vice-versa. Some of these monthly totals may constitute orders of unusual size, pattern or frequency, which would make them "suspicious" as defined in the regulation, but it would not necessarily be indicative of diversion.[148]

[146] AGI, Suspicious Order Monitoring Threshold System for McKesson Independent Retail Pharmacy Customers: Description and Rationale (May 12, 2017), Figure 1 (MCKMDL00409766 at -9772).

[147] AGI, Suspicious Order Monitoring Threshold System for McKesson Independent Retail Pharmacy Customers: Description and Rationale (May 12, 2017) (MCKMDL00409766 at -9772).

[148] AGI, Suspicious Order Monitoring Threshold System for McKesson Independent Retail Pharmacy Customers: Description and Rationale (May 12, 2017) (MCKMDL00409766 at -9772); Boggs Tr. (Jan. 17, 2019) at 362:22-363:1 ("Q. If a customer places a suspicious order, does that mean that order is likely to be diverted? A. It does not.").

## VII. McKesson's Section 55 Suspicious Order Monitoring Program Complied with the CSA and Regulations

80. The Drug Operations Manual, "McKesson's Section 55 program," is McKesson's earliest suspicious order monitoring program relevant to the current litigation.[149] McKesson's Section 55 program provides policies for the handling and distribution of controlled substances.[150] Of relevance here, McKesson's Section 55 policies cover the identification and reporting of potential suspicious orders in compliance with the CSA and the regulations.[151]

### A. Overview of McKesson's Section 55 Program

#### 1. McKesson's Section 55 Program's Detection of Suspicious Orders

81. McKesson's Section 55 program relied on both daily and monthly Controlled Substance Suspicious Order Warning Reports[152] and on reviews of controlled substances orders by order fillers and the Distribution Center management.[153] McKesson's Section 55 policies describe several daily and monthly reports generated by McKesson to track controlled substance orders and purchases.[154] Among the controlled substance reports generated under McKesson's

[149] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873).

[150] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873).

[151] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5405-11); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1918-25).

[152] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1919-20).

[153] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5410); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1923).

[154] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1919-20).

Section 55, McKesson generated daily and monthly suspicious order reports referred to by McKesson as "DU-45s."[155]

82. McKesson's daily and monthly DU-45 reports identified customers who ordered controlled substances that exceeded the three times monthly average of the Schedule II or III controlled substance.[156] McKesson's Section 55 program states that the daily and monthly DU-45s were to be reported to DEA.[157]

83. McKesson's Section 55 program outlined actions that should be taken in response to the DU-45 reports.[158] Section 55 specified that the Distribution Center Manager or other specified individuals "must review" the DU-45 report and sign to show the report was reviewed.[159] Section 55 then required that the DU-45 report be faxed "immediately" to the DEA district office.[160]

84. In addition to the Section 55 program's daily and monthly DU-45 reports, Section 55 went on to state that "[f]orwarding these reports to DEA does not relieve the Distribution Center of responsibility to review the reports and note order quantities of unusual size."[161]

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[155] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1919-20).

[156] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1919-20).

[157] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408-09); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921-22).

[158] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408-09); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921-22).

[159] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921).

[160] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921).

[161] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5409); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1922).

Instead, Section 55 requires "[w]here such transactions are noted, notify DEA by telephone call and refer to the line item of the submitted report."[162]

85. McKesson's Section 55 program also provided additional methods to identify potentially suspicious orders.

- Section 55 required that all order forms for Schedule II controlled substances "***must be reviewed and initialed by a distribution center manager*** or his or her designee properly trained in DEA Form 222 compliance ***before filling***."[163]
- Section 55 also required that "[c]ontrolled substance and List 1 product order fillers must be aware of our responsibilities. They are expected to report to management any unusual purchase request before orders are filled."[164]
- Section 55 then required that management "determine if the quantity requested will be filled entirely and record the information on the DEA Unusual Purchase Notification Log."[165]
- Section 55 explained that "it will be the responsibility of the DCM [Distribution Center Manager] ***to notify the DEA by telephone*** during daytime work hours and complete the remainder of the log. A copy of the DEA Unusual Purchase Notification Log should be mailed (Certified Mail, 'Return Receipt Requested') once a month to the DEA Regional Office in charge."[166]

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[162] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408-09); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1922).

[163] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5410) (emphasis added); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1923) (emphasis added).

[164] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5410); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1923) ("Controlled substance order fillers must be aware of our responsibilities. They are expected to report to management any unusual purchase request before orders are filled.").

[165] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5410); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1923).

[166] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5410) (emphasis added); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1923) (emphasis added).

### 2. Verification of New and Existing Customers' DEA Registrations Complied with § 1301.74(a)

86. Section 55's due diligence procedures complied with § 1301.74(a)'s requirements and DEA guidance at the time. McKesson's Section 55 program required that a designated McKesson employee verify the DEA registration of a new customer before the first shipment of controlled substances to the new customer.[167]

87. McKesson's Section 55 program also required continual monitoring of its existing customer's DEA registrations.[168] Distribution center managers reviewed DEA Number Expiration Reports to track when a customer's DEA registration was due to expire.[169] DEA Number Expiration reports allowed McKesson to track when McKesson needed to verify that the customer's registration was renewed.[170]

## B. McKesson's Daily and Monthly DU-45 Reports Satisfied the CSA and Regulatory Requirements

88. McKesson submitted suspicious order reports, referred to as "DU-45s," under its Section 55 program.[171] The industry standard at the time was to ship orders and report the orders

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[167] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5397); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1911).

[168] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5398); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1912) ("This monthly report … will list all customers, by sales territory, with DEA numbers that expire in the next 60 days. … RAMs are to sight-verify each registrant's DEA certificate listed on this report and attach a copy of the customer's renewal to the report.").

[169] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5400); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1912).

[170] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5400); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1912).

[171] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1919-20).

to DEA after the fact.[172] The DU-45s submitted by McKesson under Section 55 to DEA were suspicious order reports. DEA referred to excessive order reports as suspicious order reports and accepted those the reports as such.[173]

89. The DU-45 report stated at the top of the report that it was a "controlled substance suspicious purchase report."[174] The DU-45 reports stated at the top of each page:

> Pursuant to CFR 21, S. 1301.74(b), we are sending a copy of the monthly controlled substance suspicious purchase report for 03/07. This report reflects purchases from customers for Schedules II-V controlled substances which exceed the item monthly average for the class of trade. A listing of the parameters used are available upon request.[175]

90. McKesson's DU-45 daily and monthly reports to DEA provided DEA with information including:

- Customer information (name, address, telephone number);
- Customer's DEA registration number;
- Product's NDC number;
- Selling description (product name, dosage, manufacturer); and
- Quantity ordered.[176]

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[172] Wright Tr. (Feb. 28, 2019) at 72:4-10 ("Q. Okay. And prior -- through 2005, did you understand that it was the standard practice in the industry to submit Excessive Purchase Reports while continuing to ship product? ... A. Yes, ma'am."); Wright Trial Tr. (US v. $463,497.72) at 386:17-21 ("Q. And you understood at the time that you were making these decisions that it was standard practice in this industry to file suspicious activity reports while continuing to ship products? A. Yes, sir.").

[173] Prevoznik Tr. (May 17, 2019) Ex. 26 (US-DEA-00025672).

[174] Hilliard Tr. (Jan. 10, 2019), Ex. 10 (MCKMDL00660789 at -0790).

[175] Hilliard Tr. (Jan. 10, 2019), Ex. 10 (MCKMDL00660789 at -0790).

[176] Hilliard Tr. (Jan. 10, 2019), Ex. 10 (MCKMDL00660789 at -0790).

91. McKesson's Section 55 program described the steps required in response to the generation of the daily and monthly DU-45 reports.[177] The Distribution Center manager or another specified employee was first required to review the report and sign it.[178] The report was then faxed "immediately" to the distribution center's DEA district office.[179]

92. Section 55 required that McKesson Distribution Centers submit DU-45s to DEA. The DC manager or a designee was required to review and sign the DU-45 nightly, and fax a copy to the DC's local DEA District Office. The monthly DU-45 report was also reviewed and signed by the Distribution Center Manager or another specified employee.[180] The monthly report was then sent by certified mail to the district DEA office.[181]

93. As discussed above, the broad definition of "suspicious order" set forth in § 1301.74(b) can include large numbers of orders that are not indicative of diversion. McKesson's DU-45 reports included all orders of unusual size, pattern and frequency, even where such orders were not indicative of diversion. McKesson employees have testified that local DEA offices requested that the company stop faxing daily suspicious order reports because "they were frustrated with the frequency and size of the reports . . . and asked [McKesson] to stop clogging

[177] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408-09); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921-22).

[178] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921).

[179] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5408); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921).

[180] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5409); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1921).

[181] 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5409); 1997 McKesson Drug Operations Manual Section 55 (MCKMDL00651873 at -1922).

up the fax machines."[182] DEA personnel have testified that sometime after 2005, DEA wanted registrants to change their method of submission, because "there was a lot of paper. It took a lot of time to go through it. . . [H]alf to three-quarters of them sometimes went into the trash."[183]

### C. DEA Approved of Distributors Submitting Suspicious Order Reports to DEA After Shipping the Order

94. The industry standard at the time of McKesson's Section 55 program was to ship orders and report certain orders to DEA after the order shipped.[184] McKesson's DU-45 reports aligned with the industry standard.

95. DEA was aware of and approved the industry practice of shipping orders and reporting orders to DEA after shipping.[185] These types of reports were later referred to as "excessive purchase reports" or the "excessive purchase system."[186] DEA, however, had blessed

[182] Hilliard Tr. (Jan. 10, 2019) at 182:21-183:17; Snider Tr. (Nov. 8, 2018) at 482:10-482:24 (Testifying that DEA requested that he stop submitting daily suspicious order reports to the local DEA field office sometime in 2004 or 2005); Regulatory Section, DEA Headquarters, ODG Presentation (CAH_MDL2804_01447421 at -7435).

[183] Wright Tr. (Feb. 28, 2019) at 84:2-21.

[184] Wright Tr. (Feb. 28, 2019) at 72:4-10 ("Q. Okay. And prior -- through 2005, did you understand that it was the standard practice in the industry to submit Excessive Purchase Reports while continuing to ship product? ... A. Yes, ma'am."); Wright Trial Tr. (US v. $463,497.72) at 386:17-21 ("Q. And you understood at the time that you were making these decisions that it was standard practice in this industry to file suspicious activity reports while continuing to ship products? A. Yes, sir.").

[185] Wright Tr. (Feb. 28, 2019) at 72:4-10; Prevoznik Tr. (Apr. 17, 2019) at 121:15-19.

[186] Walker Tr. (Jan. 10, 2019) at 365:12-22; Wright Tr. (US v. $463,497.72) at 39:17–20.

these reporting systems for years.[187] DEA employee Kyle Wright testified in multiple litigations, including this one, that DEA "blessed" the "excessive purchase system."[188]

96. DEA employee Demetra Ashley further testified that DEA understood that distributors submitted these reports to DEA to comply with § 1301.74.[189] McKesson's use of the DU-45 reports to comply with § 1301.74(b) was evident on the face of its DU-45 reports, which stated on every page that "Pursuant to CFR 21, S. 1301.74(b), we are sending a copy of the monthly controlled substance suspicious purchase report."[190]

97. With respect to McKesson, DEA was aware that McKesson submitted DU-45s through several means. As I discussed above, DEA received the daily and monthly DU-45s from McKesson's distribution centers. In addition, DEA conducted cyclical audits of McKesson's distribution centers during the time that McKesson submitted DU-45s.[191] DEA would have reviewed McKesson's suspicious order monitoring program during the cyclical audits.[192] In my

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[187] Wright Tr. (Feb. 28, 2019) at 75:2-9 ("Q. And it's fair to say that that the Excessive Purchase Reports were the accepted practice by DEA for many years; is that right? ... A. As far as my experience of dealing with them when I came on, yes, ma'am."); Wright Tr. (US v. $463,497.72) at 42:19-43:2 ("A. … the DEA, some offices blessed these systems. I mean, they entered into agreements, and headquarters, unfortunately, blessed some of these systems.").

[188] Wright Tr. (Feb. 28, 2019) at 72:12-16 ("Q. Now, the Excessive Purchase System had been blessed by various DEA offices; is that right? … A. Yes, ma'am.").

[189] Ashley Tr. at 30:14-17 ("Q. Okay. Do you know why the registrants, the distributors were submitting this type of report? A. Yeah, required by regulation."); Ashley Tr. at 30:18-31:4 ("Q. Okay. And so in other words, what you understood -- am I correct that your understanding is that the distributors were submitting these excessive purchase reports in order to meet their obligations with their suspicious order reporting obligations under 1301.74? ... A. Yes.").

[190] McKesson Monthly Controlled Substance Suspicious Purchase Report (Apr. 3, 2007) (MCKMDL00660789 at -0790).

[191] Hilliard Tr. at 175:12-176:4 ("A. … There was DEA inspections that had occurred in our facilities and there was never an issue with that.").

[192] Rafalski Tr. (May 13, 2019) at 343:3-22 (A. … It's a three-pronged investigation: security, recordkeeping and accountability."); Prevoznik Tr. (Apr. 17, 2019) at 130:13-131:14 ("A. … We're going to look at various things to make the determination on what is going on.").

experience and, as was confirmed by other witnesses who worked at DEA, DEA would have informed McKesson during an audit if the DU-45 reports did not comply with § 1301.74(b).[193] During the cyclical audits DEA conducted of McKesson while McKesson submitted DU-45s, DEA never raised any issues with McKesson's submission of DU-45s to DEA.[194]

### D. McKesson's Section 55 Program Complied with the CSA and Regulations

98. It is my opinion that McKesson's Section 55 complied with the requirements set forth in the CSA, implementing regulations, and relevant DEA guidance at the time. If I were to visit a McKesson DC as a DEA Diversion Investigator to review McKesson's Section 55 policy and inspect McKesson operations when the Section 55 suspicious order program was in effect, I would have reported that it was compliant with all requirements. I would have also concluded that McKesson's Section 55 program was properly designed to combat diversion as it was understood at the time.

[193] Prevoznik Tr. (Apr. 17, 2019) at 131:15-23 ("Q. And if either in the pre-registration process or in the audit process the DEA determines that a registrant's system is not adequately detecting suspicious orders, is that something that is conveyed to the registrant? A. Yeah, we -- we would tell them, you need to add something."); Prevoznik Tr. (Apr. 18, 2019) at 461:13-21 ("Q. Okay. And the registrants who are visited by DEA field office personnel can rely on the information that they receive from DEA field division personnel regarding SOMs systems, true? … A. Yeah, they get guidance."); Rafalski Tr. (May 13, 2019) at 342:9-343:2 ("Q. So if McKesson's Section 55 program had been out of compliance with federal regulations and DEA was conducting audits of the McKesson facilities, wouldn't DEA have told McKesson during its annual audits that its program was out of compliance? A. I would have an expectation that if a person was to go on site and actually review the system, that I would have an expectation that there -- maybe should make some comment or do some corrective action.").

[194] Hilliard Tr. at 175:21-176:4 ("A. This was part of the Suspicious Order Task Force. This was the format for which industry came to the conclusion to provide this information to the DEA and DEA was good with it. There was DEA inspections that had occurred in our facilities and there was never an issue with that. So this is the format for which the original documentation was supplied to DEA.").

### E. McKesson's Section 55 Program Followed Models of Industry and DEA Approved of Industry Practice

99. McKesson's Section 55 program followed the models that DEA and industry had created at the time.

#### 1. The 1998 Suspicious Order Task Force Report Reflects Industry Standards for Controlled Substances, Including McKesson's Section 55 Program

100. DEA and distributors regularly met prior to the Distributor Initiative briefings concerning the reporting of suspicious orders to DEA. One collaboration between DEA and industry was the Suspicious Order Task Force ("Task Force"), which was formed in 1997.[195] The Task Force included representatives from industry, law enforcement, and regulatory agencies.[196] Two DEA officials participated on the Task Force.[197] The Task Force developed guidelines to identify signs of "suspicious orders" in various parts of the industry.[198]

101. The work of the Task Force was not limited to preventing the illegal production and abuse of methamphetamine. The Task Force Report applied the industry standards used for controlled substances at the time to List 1 chemicals. Recommendations in the Task Force's Report like the use of automated tracking systems for "suspicious order report" applied for "List I Chemicals **and** Schedule II – V Controlled Substances."[199]

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[195] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2211).

[196] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2211).

[197] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2217).

[198] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2211).

[199] Report to the U.S. Attorney General by the Suspicious Orders Task Force (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2247).

102. The Task Force Report included a proposed formula that could be used in automated suspicious order monitoring systems.[200] The proposed formula included:

- Calculating monthly averages based on the last 12 months of purchasing; and
- Setting monthly thresholds that were 3 times the monthly average for purchases involving Schedule II substances.[201]

103. The Task Force's Report recommended that one report should be submitted to DEA for Schedule II-V controlled substances, and one report should be submitted to DEA for List 1 chemicals.[202]

**2. Chemical Handler's Manual**

104. DEA first published the "Chemical Handler's Manual: A Guide to Chemical Control Regulations" in June 2002. The Chemical Handler's Manual has been updated several times by DEA since 2002. DEA issued the Chemical Handler's Manual "for the purpose of explaining the Controlled Substances Act (CSA) and its implementing regulations."[203]

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[200] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2247) ("This formula is used to calculate the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious.").

[201] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2247).

[202] Report to the U.S. Attorney General by the Suspicious Orders Task Force (Oct. 1998) (CAH_MDL_PRIORPROD_HOUSE_0002207 at -2247) ("At the end of each month, a report will be transmitted to DEA (separate reports List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customers whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.") (emphasis added).

[203] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8695).

105. In Appendix E-3, the Chemical Handler's Manual outlines the same formula developed by the Suspicious Order Task Force in 1998. The formula for reporting suspicious orders in Appendix E-3 is entitled "Suspicious Order Reporting System for Use in Automated Tracking Systems."[204] The Chemical Handler's Manual explains that the formula is a "voluntary formula" that "is for use by distributors to wholesale and retail levels."[205] The Chemical Handler's Manual goes on to explain that "[t]he formula calculates the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious and therefore require reporting to DEA."[206] The Chemical Handler's Manual's formula includes:

- Setting a monthly average using information about the customer's last twelve months of purchases; and
- Setting a monthly threshold amount at 3x the monthly average for purchases that contain Schedule II controlled substances.[207]

106. For example, if the monthly average of the controlled substances was three units for that product, then the monthly threshold for that product would have been 9 units.

[204] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8735).

[205] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8735).

[206] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8735).

[207] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8735).

107. The Chemical Handler's Manual recommends that a distributor provide "separate reports for List I Chemicals and Schedule II-V Controlled Substances" to DEA.[208] The Chemical Handler's Manual also recognizes that using computers to report suspicious orders to DEA is the "only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious."[209]

### 3. DEA Blessed Registrants' Suspicious Order Monitoring Programs

#### a) DEA Wrote Letters that Approved ABDC's Suspicious Order Monitoring Program

108. One example of DEA blessing a distributor's suspicious order monitoring program is DEA's approval of ABDC's suspicious order monitoring program that DEA and ABDC developed together. The suspicious order monitoring program that ABDC developed with DEA involved a computer program that compared a customer's controlled substance orders to a standard, which was an average of that customer's prior four months of orders.[210] Under ABDC's proposed monitoring program, ABDC would print on a summary report any customer orders that exceeded the past four month average by a specified amount.[211] After that order was

[208] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8735).

[209] U.S. Department of Justice, Drug Enforcement Administration, "Chemical Handler's Manual: A Guide to Chemical Control Regulations," (January 2004) (CAG_MDL_PRIORPROD_DEA07_01198690 at -8735).

[210] Chris Zimmerman Letter to DEA (Sept. 30, 1996) (ABDCMDL00269355 at -9356).

[211] Chris Zimmerman Letter to DEA (Sept. 30, 1996) (ABDCMDL00269355 at -9356).

processed, ABDC faxed the report to the appropriate DEA field office.[212] As stated in ABDC's letter to DEA, ABDC's program involved shipping the orders that ABDC reported to DEA.[213]

109. With this knowledge, DEA responded to ABDC's proposed automated suspicious order monitoring program on October 29, 1996. DEA wrote that "[w]e have reviewed your proposal and feel that it could be a viable alternative to the current system."[214] DEA also acknowledged that it understood that program involved ABDC shipping the orders that appeared on the report to DEA. Specifically, DEA recognized that the report to DEA would include the "active ingredient volume ordered ***and shipped.***"[215] DEA closed its letter to ABDC by stating: "We look forward to working with you on this new project which we, too, hope will lead to a more efficient suspicious order reporting system."[216]

110. ABDC tested its new system on a limited scale. After this testing, DEA wrote to ABDC that "DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion that which is not only useful overall, but is also responsive to the needs of individual DEA offices."[217]

111. The letter that ABDC received from DEA on July 23, 1998, was "Approve Suspicious Order Monitoring Program."[218] In the letter, DEA approved of ABDC's suspicious

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[212] Chris Zimmerman Letter to DEA (Sept. 30, 1996) (ABDCMDL00269355 at -9356).

[213] Chris Zimmerman Letter to DEA (Sept. 30, 1996) (ABDCMDL00269355 at -9356); DEA Letter to Chris Zimmerman (October 29, 1996) (ABDCMDL00315789 at -5789).

[214] DEA Letter to Chris Zimmerman (October 29, 1996) (ABDCMDL00315789 at -5789).

[215] DEA Letter to Chris Zimmerman (October 29, 1996) (ABDCMDL00315789 at -5789) (emphasis added).

[216] DEA Letter to Chris Zimmerman (October 29, 1996) (ABDCMDL00315789 at -5790).

[217] DEA Letter to Chris Zimmerman (July 23, 1998) (US-DEA-00025671).

[218] DEA Letter to Chris Zimmerman (July 23, 1998) (US-DEA-00025671).

order monitoring program. DEA wrote that "[t]his is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal regulation."[219]

**b) ABDC's Suspicious Order Monitoring Program and McKesson's Section 55 Program Shared Key Features**

112. McKesson's Section 55 program was similar to ABDC's program in key features. Most importantly, McKesson's Section 55 program and the ABDC program as described in DEA's approval letters both involved reporting suspicious orders on a daily and monthly basis to DEA.[220] DEA expressly approved of distributors submitting automated reports of suspicious orders after the orders shipped on a daily and monthly basis to DEA.[221] In addition, DEA approved implementation of the system with after-the-fact reporting of suspicious orders.[222]

113. Another critical feature shared by both McKesson's Section 55 program and ABDC's program is that both programs detected suspicious orders using a multiplier of the average of the customer's prior monthly purchases.[223] Both systems created reports of customer

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[219] DEA Letter to Chris Zimmerman (July 23, 1998) (US-DEA-00025671).

[220] Rafalski Tr. (May 13, 2019) at 341:2-11 (Q. … And both McKesson and ABDC's systems, they report suspicious orders on a daily or monthly basis after the order has been shipped. That was part of the old program, right? A. Well, based on that algorithm, they were reporting -- making reports on a monthly basis to the DEA, yes, sir."); 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07).

[221] DEA Letter to Chris Zimmerman (July 23, 1998) (US-DEA-00025671).

[222] DEA Letter to Chris Zimmerman (July 23, 1998) (US-DEA-00025671); Prevoznik Tr. (May 17, 2019) at 1139:10-16 (Q. Okay. Mr. Prevoznik, the DEA approved for implementation nationwide a suspicious order monitoring system that reported suspicious orders to the DEA on a daily basis after the report -- after the orders had already been shipped, correct? A. Yes."), Prevoznik Tr. (May 17, 2019) at 1157:15-21 (Q. Okay. And the system that was designed, that the DEA approved to implement, using your words, had after-the-fact reporting, correct? … A. Yes.").

[223] Rafalski Tr. (May 13, 2019) at 340:19-341:1 ("Q. Both McKesson and ABDC's systems, they used a multiplier of the customer's prior monthly purchase averages to detect suspicious

orders that exceeded the multiplier and sent those reports to DEA after the order shipped on a daily and monthly basis.[224] In a letter to ABDC, DEA described ABDC's program: "Customer's orders that exceed their four month average order history by an as yet unspecified percentage would be shown on a summary report that would be sent to the appropriate Drug Enforcement Administration (DEA) field office on a daily basis."[225] DEA referred to the reports generated using the multiplier as suspicious order reports in a DEA letter to ABDC.[226]

114. McKesson's Section 55 program shared critical features with ABDC's suspicious order monitoring program in use at the same time. DEA's approval of such features with respect to ABDC's program also constitute DEA's acceptance of the same features in McKesson's program.[227]

## VIII. Diversion Trends and Changing Technology

115. Pharmaceutical diversion has meaningfully changed over the past twenty years.[228] Rogue Internet pharmacies and pill mills, for example, were unprecedented criminal diversion

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orders, correct? A. They did use a multiplier."); 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406).

[224] Chris Zimmerman Letter to DEA (Sept. 30, 1996) (ABDCMDL00269355 at -9356); McKesson Section 55 (MCKMDL00545378 at -5406-5407); 2000 McKesson Drug Operations Manual Section 55 (MCKMDL00545378 at -5406-07).

[225] DEA Letter to Chris Zimmerman (Oct. 29, 1996) (ABDCMDL00315789 at -5789).

[226] DEA Letter to Chris Zimmerman (Oct. 29, 1996) (ABDCMDL00315789 at -5789); Prevoznik Tr. (May 17, 2019) at 1109:15-1110:15 (Q. Okay. They -- the DEA says suspicious order, right? … A. Yeah."); 1118:2-1118:10 ("Q. But Tom refers to it as a monthly suspicious order report, correct? A. Right.").

[227] Wright Tr. (Feb. 28, 2019) at 72:12-16 ("Q. Now, the Excessive Purchase System had been blessed by various DEA offices; is that right? ... A. Yes, ma'am.").

[228] Boggs Tr. (Jan. 17, 2019) at 356:14-22 ("A. There's different types of schemes that can occur that would cause a – what I would consider a trend. We've – we've seen diversion trends, such as rogue internet pharmacies, be a diversion trend. It's a massive criminal scheme. We've seen pill mills in Florida. That's a diversion trend and is a criminal scheme."); Boggs Tr. (July 19, 2018) at 80:22-81:12.

schemes that had never been seen before in the country.[229] Highly specific red flags of diversion were associated with rogue Internet pharmacies and pill mills that may not be useful in detecting other diversion schemes.[230] Technology also has advanced significantly over the past twenty years, and McKesson worked hard to incorporate these developments in technology into its anti-diversion program.

### A. Rise of Rogue Internet Pharmacies

116. A significant diversion trend that emerged in the early 2000s was rogue Internet pharmacies.[231] Rogue Internet pharmacies were the primary focus of DEA's pharmaceutical diversion efforts during the early- to mid-2000s.[232] Mr. Rannazzisi wrote his letters to distributors that are dated September 27, 2006, and December 27, 2007, in the context of rogue Internet pharmacies.[233] The red flags that Mr. Rannazzisi identified, for example, are focused on rogue Internet pharmacies.[234] The red flags identified for one type of diversion scheme may be

[229] Boggs Tr. (Jan. 17, 2019) at 145:14-146:3 ("A. I don't know that that's necessarily the case. We're – we're talking about a couple of significant diversion schemes that occurred at a period of time that have never – never happened before in this country. So the red flags sometimes are very specific to that criminal scheme that may not be applicable to other types of schemes or other day-to-day operations of regular pharmacies or practitioners."); Boggs Tr. (July 19, 2018) at 80:22-81:12.

[230] Boggs Tr. (Jan. 17, 2019) at 145:14-146:3; Boggs Tr. (July 19, 2018) at 80:22-81:12.

[231] Boggs Tr. (Jan. 17, 2019) at 295:21-296:11; Boggs Tr. (July 19, 2018) at 33:2-33:18; 38:24-39:8 ("A. I believe that during that time frame that the rogue Internet pharmacy schemes were a relatively new scheme to both law enforcement and to the health care industry, and it was sent out as a reminder of potentially evolving red flags that they should be cognizant of in fulfilling their obligations to report suspicious orders."); Prevoznik Tr. (Apr. 17, 2019) at 157:18-158:21.

[232] Wright Tr. (Feb. 28, 2019) at 223:4-224:4.

[233] September 27, 2006 Dear Registrant Letter (MCKMDL00478906); December 27, 2007 Dear Registrant Letter (MCKMDL00478910); Boggs Tr. (July 19, 2018) at 36:20-38:6; 53:25-55:4.

[234] Boggs Tr. (Jan. 18, 2019) at 90:23-91:19; Boggs Tr. (July 19, 2018) at 36:20-38:6; 53:25-55:4.

specific to that type of diversion, and may not apply to other types of diversion schemes.[235] Rogue Internet pharmacies became virtually nonexistent after the passage of the Ryan Haight Act in 2008.[236]

### B. Rise of Pill Mills

117. Pills mills were the diversion trend that followed the decline of rogue Internet pharmacies.[237] In the late 2000s, a significant criminal diversion scheme related to rogue pain clinics, which are frequently referred to as "pill mills," emerged in Florida.[238] Pill mills typically involved illegal prescriptions for controlled substances written by a doctor registered with DEA to write prescriptions for controlled substances.[239] The doctor would write prescriptions for patients who did not have a legitimate medical need for medication.[240] The doctor would write these illegal prescriptions in exchange for money and typically without performing a medical evaluation.[241]

### C. Improvements in Technology Used for Anti-Diversion Efforts

118. The technology used to combat diversion has changed dramatically over the past 30 years. Computers, for example, were virtually non-existent when the CSA was passed in the 1970s. Computer technology was introduced over the last 20 years, and capabilities of computer

[235] Boggs Tr. (Jan. 17, 2019) at 145:14-146:3.

[236] Boggs Tr. (Jan. 17, 2019) at 80:22-81:12.

[237] Prevoznik Tr. (Apr. 18, 2019) at 490:14-491:16.

[238] Boggs Tr. (Jan. 17, 2019) at 137:5-13; 144:19-23; Boggs Tr. (July 19, 2018) at 90:21-25; Prevoznik Tr. (Apr. 18, 2019) at 490:14-491:16.

[239] Boggs Tr. (Jan. 17, 2019) at 358:23-360:4; Wright Tr. (Feb. 28, 2019) at 224:14-224:25.

[240] Boggs Tr. (Jan. 17, 2019) at 358:23-360:4; Wright Tr. (Feb. 28, 2019) at 224:14-224:25.

[241] Boggs Tr. (Jan. 17, 2019) at 358:23-360:4; Wright Tr. (Feb. 28, 2019) at 224:14-224:25.

programs have advanced at a very fast speed. Computers now play a central role in anti-diversion programs.

119. Methods of communicating with DEA have also changed significantly since the passage of the CSA. Distributors often communicated with DEA by phone or using hard-copy letters and triplicate forms back in the time period when the CSA was passed. Through the mid-2000s, distributors would rely on fax machines to submit suspicious order reports and other documents to DEA. With the development of computers, distributors began to incorporate computer technology into their suspicious order monitoring programs and their communications with DEA.

120. It is critical to remember how much technology has advanced when comparing early suspicious order monitoring programs to the programs in use by distributors at this time. The technology that is used today simply did not exist during earlier iterations of suspicious order monitoring programs. The algorithms and technology used by McKesson today to monitor for suspicious orders were only technologically possible in recent years and took McKesson years to develop.

**D. The CSA and Its Regulations Have Not Changed**

121. The regulatory framework that came into existence in the 1970s has not been updated or revised to account for the significant changes in technology and pharmaceutical diversion. The CSA and its regulations are basically unchanged since the 1970s.[242] Congress and DEA did not update the CSA and regulations to adapt to the significant advancements in technology, such as developments in computers and the algorithms used to detect suspicious

[242] Prevoznik Tr. (Apr. 17, 2019) at 90:4-13; Rannazzisi Tr. (Apr. 26, 2019) at 68:1-14, 253:19-23; Wright Tr. (Feb. 28, 2019) at 125:20-126:11.

orders. The CSA and regulations also have not evolved to address the diversion trends that have emerged over the years, such as rogue Internet pharmacies and pill mills.[243]

## IX. DEA Only Offered Informal Guidance in Response to Changing Diversion Trends and Advancements in Technology

122. DEA's response to constantly shifting diversion trends and advancements in technology was slow and incomplete.[244] DEA did not, for example, work with Congress to update the CSA and the applicable regulations in response to changes in technology and pharmaceutical diversion.[245] DEA also did not provide clear guidance or clarifications in written materials sent to the industry. Instead, DEA engaged in one-on-one meetings with certain registrants in what DEA called the "Distributor Initiative."[246]

### A. DEA's Distributor Initiative

123. Beginning in August 2005, DEA met with distributors individually as part of its "Distributor Initiative Program."[247] The individual briefings continued through 2010 and then restarted in 2013.[248] During each briefing, DEA presented a PowerPoint presentation entitled

[243] Prevoznik Tr. (Apr. 17, 2019) at 90:4-13; Rannazzisi Tr. (Apr. 26, 2019) at 68:1-14, 253:19-23; Wright Tr. (Feb. 28, 2019) at 125:20-126:11.

[244] Rannazzisi Tr. (Apr. 26, 2019) at 68:1-14, 253:19-23; Wright Tr. (Feb. 28, 2019) at 125:20-126:11.

[245] Prevoznik Tr. (Apr. 17, 2019) at 136:8-24; 288:11-22.

[246] Prevoznik Tr. (Apr. 17, 2019) at 136:8-24; 288:11-22; Wright Tr. (Feb. 28, 2019) at 189:16-.

[247] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859); Memorandum from Michael Mapes to Joseph Rannazzisi (Aug. 23, 2005) (US-DEA-00000352); Memorandum from Michael Mapes to William J. Walker (Aug. 16, 2005) (US-DEA-00000147).

[248] Wright Tr. (Feb. 28, 2019) at 97:20-24; Prevoznik Tr. (Apr. 17, 2019) at 200:24-201:11.

"Internet Pharmacy Data."[249] The presentation was approved by Joseph Rannazzisi.[250] In 2005, the primary presenters for the briefings from DEA were Michael Mapes and Kyle Wright.[251] The presentations were substantively identical.[252] The purpose of these briefings was to discuss new diversion trends involving rogue Internet pharmacies.[253]

124. I understand that DEA met with McKesson as part of DEA's Internet briefings on September 1, 2005. The meeting was memorialized by DEA in a memorandum written by Michael Mapes to Joseph Rannazzisi, and a copy of the slides presented to McKesson was attached.[254]

125. During the meetings with distributors, I understand DEA provided an overview of the common characteristics of Internet pharmacies.[255] DEA highlighted why the activities of rogue Internet pharmacies were illegal.[256] DEA identified two customers of McKesson "who have ordered substantial quantities of hydrocodone products."[257] DEA used ARCOS data to

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[249] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -861).

[250] Wright Tr. (Feb. 28, 2019) at 90:19-24.

[251] Wright Tr. (Feb. 28, 2019) at 89:22-90:2; 91:4-8.

[252] Wright Tr. (Feb. 28, 2019) at 92:18-21.

[253] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6859 ("The purpose of the meeting was to address the illegal domestic Internet pharmacy problem and their source of supply."); Wright Tr. (Feb. 28, 2019) at 98:14-99:6.

[254] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859).

[255] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6859).

[256] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6859).

[257] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6859).

identify these customers.[258] DEA asked McKesson to "review in-depth the purchasing patterns and quantities of their customers," which McKesson acknowledged.[259] DEA further agreed to notify McKesson if the E-Commerce Operations section of DEA identified a "highly suspicious pharmacy" to which McKesson distributed.[260] McKesson agreed that it would review the ordering patterns of its customers in view of the materials that DEA had presented.[261] McKesson subsequently terminated the pharmacies identified by DEA as customers.[262]

126. During the Internet briefings, DEA focused on small independent pharmacies that lacked a brick-and-mortar presence.[263] DEA's focus during the Internet briefings was not on retail chain pharmacies such as CVS, Rite-Aid and Walgreens, and DEA emphasized that Internet pharmacies were "unrelated to brick and mortar pharmacy."[264]

127. DEA identified controlled substances that were the primary products dispensed by Internet pharmacies, which Mr. Rannazzisi referred to as "lifestyle drugs" in his 2006 Dear

[258] Wright Tr. (Feb. 28, 2019) at 96:23-97:4.

[259] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6859).

[260] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6860).

[261] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6860).

[262] Letter from Paul Julian to Joseph Rannazzisi (Jan. 18, 2006) (MCKMDL00571361 at -1363) ("Nevertheless, in light of DEA's strong assertion at the January 6, 2006 meeting that these pharmacies are "Internet pharmacies" McKesson as of January 9, 2006, has terminated sales of controlled substances to all six pharmacies.")

[263] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6861).

[264] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6859).

Registrant letter, as hydrocodone, alprazolam, and phentermine.[265] DEA explained that pharmacies ordering high volumes of those pharmaceutical products without a range of other products could be an issue to consider when identifying possible rogue Internet pharmacies.[266]

128. Although Mr. Wright confirmed the Internet briefings with distributors were "when the introduction from and transition from the Excessive Purchase System into the Suspicious Ordering System occurred," the "Internet Pharmacy Data" presentation did not instruct McKesson to "block" suspicious orders.[267] The presentation also did not include a "do not ship" requirement for suspicious orders.[268] Instead, DEA says it "cannot tell a distributor if an order is legitimate or not."[269] DEA also says that a "distributor must determine which orders are suspicious and make a sales decision."[270] This statement provides distributors with the discretion to make a sales decision about whether to ship the materials.

129. The presentation given to McKesson also does not include statements requiring McKesson to change or alter its suspicious order monitoring program by a particular date.[271]

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[265] September 27, 2006 Dear Registrant Letter (MCKMDL00478906 at -8908) ("Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.").

[266] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6862).

[267] Wright Tr. (Feb. 28, 2019) at 101:11-102:10; Wright Trial Tr. (US v. $463,497.72) at 387:21-24; Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6861-6874).

[268] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6861-6874).

[269] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6868).

[270] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6868).

[271] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859); Wright Tr. (Feb. 28, 2019) at 123:17-124:7; 125:5-8.

The memorandum written by Michael Mapes concluded by stating that the meeting ended "with each party having a clearer understanding and agreement as to how [to] best address the sources of supply to Internet pharmacies."[272]

### B. DEA's New Guidance: Transitioning from Excessive Purchase Reporting to Suspicious Order Monitoring

130. The distributor briefings marked when the "introduction from and transition from the Excessive Purchase System into the Suspicious Ordering System occurred."[273] DEA did not provide deadlines by which distributors must implement new systems, but expected the transition to be gradual.[274] During the transition, DEA continued to accept Excessive Purchase Reports as meeting the requirements of the CSA and its regulations.[275]

131. In shifting its guidance, DEA did not work with Congress to amend the Controlled Substances Act or applicable regulations or publish any notifications of rulemaking.[276] DEA did not want to provide registrants with a model system or approvals as it had in the past.[277] DEA was concerned that the previously approved Excessive Purchase

[272] Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859 at -6860).

[273] Wright Tr. (Feb. 28, 2019) at 101:11-102:10; Wright Tr. (US v. $463,497.72), at 43:3-14.

[274] Wright Tr. (Feb. 28, 2019) at 124:2-125:8.

[275] Wright Tr. (Feb. 28, 2019) at 72:4-16; 124:2-7; Ashley Tr. (Mar. 15, 2019) at 30:14-17, 30:18-31:4.

[276] Wright Tr. (Feb. 28, 2019) at 125:20-126:11.

[277] Wright Tr. (Feb. 28, 2019) at 132:3-18, 200:12-16; December 27, 2007 Dear Registrant Letter (MCKMDL00478910) ("Past communications with DEA whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."); Ashley Tr. (Mar. 15, 2019) at 30:14-17; 30:18-25-31:4.

Systems had become fixed and not able to encompass changing diversion trends.[278] Instead, DEA decided to offer only "limited" guidance to distributors.[279]

132. It turned out that this approach confused distributors and DEA diversion investigators as to what was expected for compliance with the CSA, in part, because the Excessive Purchase Reports were the only known CSA-compliant systems to DEA and industry alike.[280] And, as DEA acknowledged, implementing the new requirements would be "harder."[281] Accordingly, DEA wrote letters to the industry to provide additional information on its new expectations without modifying or amending the CSA and its regulations.[282]

133. Notable within these letters are DEA's affirmative statement that "Past communications with DEA whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[283] In 2010, five years after the start of the Distributor Initiative, DEA instructed the industry that "DEA will no longer accept Excessive Purchase Reports. Previously excessive purchase reports were received after drugs had already been shipped by

[278] Wright Tr. (Feb. 28, 2019) at 115:17-116:12; 119:23-120:10; 127:6-128:12; 135:7-15.

[279] Wright Tr. (Feb. 28, 2019) at 116:13-24.

[280] Wright Tr. (Feb. 28, 2019) at 120:12-18, 120:23-3, 121:7-16.

[281] Wright Tr. (Feb. 28, 2019) at 123:2-16.

[282] September 27, 2006 Dear Registrant Letter (MCKMDL00478906); February 7, 2007 Dear Registrant Letter (MCKMDL00615308); December 27, 2007 Dear Registrant Letter (MCKMDL00478910); June 12, 2012 Dear Registrant Letter (MCKMDL00449807); Rannazzisi Tr. (Apr. 26, 2019) at 242:19-243:25; 335:22-336:25.

[283] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

registrants."[284] Despite this limited guidance from DEA, it continued to refuse to approve specific systems or provide a model system, and DEA did not change the CSA or its regulations.

**1. "Do Not Ship" Requirement**

134. Neither the CSA nor any of the applicable federal regulations include a "do not ship" requirement or command registrants to "block" all orders that meet the definition of "suspicious order" from Section 1301.74(b).[285] As discussed above, at least through the Distributor Initiative, it was "standard practice" in the industry to report orders meeting the definition of "suspicious orders" while shipping those orders.[286]

135. And, although the Distributor Initiative may have been the start of a "transition" from the Excessive Purchase Reports systems into the modern suspicious ordering monitoring systems, DEA's presentation did not instruct McKesson to "block" or "do not ship" all "suspicious orders."[287] The CSA and its regulations still remained unchanged.

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[284] Regulatory Section, DEA Headquarters, ODG Presentation (CAH_MDL2804_01447421 at -7435).

[285] 21 C.F.R. § 1301.74(b); Rannazzisi Tr. (May 15, 2019) at 534:19-21 ("Q. Do the words 'do not ship' appear in this regulation? A. No, ma'am."); Ashley Tr. at 27:20-28:3 ("Q. Does the regulation say anything about whether a registrant can ship an order that it has reported as suspicious? A. It doesn't say if they should ship it.").

[286] Wright Tr. (Feb. 28, 2019) at 72:4-10 ("Q. And prior – through 2005, did you understand that it was the standard practice in the industry to submit Excessive Purchase Reports while continuing to ship product? A. Yes, ma'am."); Regulatory Section, DEA Headquarters, ODG Presentation (CAH_MDL2804_01447421 at -7435).

[287] Wright Tr. (Feb. 28, 2019) at 101:22-102:10 ("'Answer: Well, it became -- it was a matter of very intense discussion in developing what was called the distributor briefing. Because that's when the change occurred. And that's when the introduction from and transition from the Excessive Purchase System into the Suspicious Ordering System occurred.' That was the testimony you gave under oath, correct? … A. Yes, ma'am."); Wright Tr. (US v. $463,497.72) at 43:3-14; Wright Trial Tr. (US v. $463,497.72) at 387:21-24 ("Q. So I'm trying to figure out where in this slide it says, if you file a suspicious activity report, you are to stop shipping. A. It doesn't say that."); Memorandum from Michael Mapes to Joseph Rannazzisi (Oct. 20, 2005) (MCKMDL00496859).

**a) Mr. Rannazzisi introduced "Do Not Ship" in his 2007 letter to industry**

136. Following the Distributor Initiative with McKesson, DEA purported to provide additional clarifications to distributors as the Distributor Initiative developed. For example, DEA met with McKesson again on January 3, 2006.[288] Mr. Rannazzisi sent distributors a letter dated September 27, 2006, which is referred to as the 2006 Rannazzisi Letter. DEA sent distributors the same letter a second time on February 7, 2007,[289] followed by another letter on December 27, 2007.[290] Mr. Rannazzisi's letter to distributors dated December 27, 2007, is frequently referred to as the 2007 Rannazzisi Letter. DEA sent a fourth letter that was dated June 12, 2012.[291] These letters, collectively, are called the "Dear Registrant" letters.

137. Although DEA states the purpose of the Dear Registrant letters was to "reiterate" the duties of distributors under the CSA, these letters purported to offer clarifications on topics discussed in distributor briefings and introduced requirements that extended beyond those imposed by the CSA and its regulations.[292]

138. For example, the 2006 Rannazzisi Letter contains a list of questions that a distributor registrant "may wish to inquire with the ordering pharmacy about."[293] The questions focused on issues that had arisen in the context of rogue Internet pharmacies. Further, the 2007

[288] Memorandum from Michael Mapes to Joseph Rannazzisi (Jan. 23, 2006) (MCKMDL00496876).

[289] February 7, 2007 Dear Registrant Letter (MCKMDL00615308).

[290] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[291] June 12, 2012 Dear Registrant Letter (MCKMDL00449807).

[292] September 27, 2006 Dear Registrant Letter (MCKMDL00478906); December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[293] September 27, 2006 Dear Registrant Letter (MCKMDL00478906 at -8908).

Rannazzisi Letter stated for the first time in an official DEA communication what has become known as the "do not ship" policy: "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion."[294]

139. The 2007 Rannazzisi Letter also outlined the "know your customer" policy: "Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."[295] The 2007 Rannazzisi Letter also withdrew DEA's prior approvals of suspicious order monitoring programs, including McKesson's: "Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[296]

140. Although the statements in the 2007 Rannazzisi Letter were the first time DEA provided these statements in writing to registrants,[297] DEA disclosed some of the concepts to the industry three months earlier at DEA's Pharmaceutical Industry Conference on September 11-12,

[294] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[295] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[296] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[297] Rannazzisi Tr. (May 15, 2019) at 531:20-532:3 ("Q. Prior to the fall of 2005 and since 1970, where were the requirements you spoke of written down somewhere and given to distributors? A. I don't recall any -- any type of document or guidance document where the distributors were told to do certain things prior to 2005 that were related to maintaining effective controls against diversion.").

2007.[298] At this conference, DEA along with AmerisourceBergen introduced the terminology of "know your customer" and "do not ship."[299] Among other topics, DEA explained that "Know Your Customer" Due Diligence investigations [should be] completed on all new Retail and Wholesale Accounts" and "Retail chain pharmacies are exempted."[300] AmerisourceBergen and DEA explained that "[h]istorically Controlled Substance / Listed Chemical order monitoring has been based on a ship and report process," but new processes "[should] now [be] based on: identify, capture, investigate, and report suspicious orders; all **prior to shipment**."[301]

**b) DEA changed its Diversion Investigator Manual to include "Do Not Ship" following Mr. Rannazzisi's 2007 letter to industry**

141. The DEA Diversion Investigator Manual, which was an internal DEA resource for all Diversion Investigators, confirmed DEA's new "do not ship" guidance. For example, Section 5126 of the 1996 version of the DEA Diversion Investigator Manual states: "The responsibility for making the decision to ship rests with the supplier."[302] The Diversion Investigator's Manual then provides the following guidance:

> **Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that**

[298] Prevoznik Tr. (May 17, 2019) Ex. 29 (DEA Meetings & Events, Pharmaceutical Industry Conference: September 11 & 12, 2007 - Houston, Texas, *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html); Prevoznik Tr. (May 17, 2019) Ex. 30 (ABDCMDL00037184 at -7188-90).

[299] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7190-91).

[300] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7190).

[301] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7192) (emphasis in original).

[302] Diversion Investigators Manual, 04/16/1996 (CAH_MDL2804_02203353 at -3356).

> **is a detriment to the public health and safety as set forth in 21 USC 823 and 824.** Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted. An investigation will be conducted for possible violation of the Controlled Substances Act and Regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.[303]

142. The 1996 Manual states that not all orders meeting the definition of "suspicious orders" give a distributor "reason to believe that they are destined for the illicit market," and only those that give rise to such a belief should not be shipped.[304] The statement found in the 1996 Manual is different than the "do not ship" policy applied to all orders meeting the definition of "suspicious order" under Section 1301.74(b) that DEA imposed after the Distributor Initiative. The 1996 Manual was the operative Diversion Investigators Manual during my time as a Diversion Investigator. In my experience, this is consistent with how DEA understood distributors operated during this time period.

143. In 2011, DEA changed the language of Section 5126 in the Diversion Investigators Manual to reflect DEA's new "do not ship" policy:

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[303] Diversion Investigators Manual, 04/16/1996 (CAH_MDL2804 02203353 at -3356-57) (emphasis added).

[304] Diversion Investigators Manual, 04/16/1996 (CAH_MDL2804_02203353 at -3356-57).

> A. Title 21 U.S.C. § 823 requires manufacturers and distributors to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. 21 C.F.R. §1301.74(b) further requires registrants to design and operate a system to disclose to the registrant suspicious orders, and report such orders to their local field office. By its very nature, an order is a request to purchase controlled substances and has not yet been filled. Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.
>
> B. Registrants may fill an order that was previously deemed suspicious only after such time as a thorough review has been conducted and findings appropriately documented, as outlined in the Dear Registrant Letter, dated September 27, 2006.[305]

144. With this change to the Manual, DEA informed Diversion Investigators that "[r]egistrants may fill an order that was previously deemed suspicious only after such time as a thorough review has been conducted and findings appropriately documented, as outlined in the Dear Registrant Letter, dated September 27, 2006."[306] The policy as stated here is actually in the 2007 Rannazzisi Letter, not the 2006 Rannazzisi Letter.[307] But, more importantly, this policy change is not reflected in the CSA or its implementing regulations. This change to DEA policy and guidance occurred after the Distributor Initiative meetings with McKesson.

145. I am aware of certain isolated statements, made by DEA personnel to various entities in the 1980s and 1990s, that refer to the requirements for handling of "suspicious orders."[308] Some of these documents convey that registrants should report "suspicious orders" to DEA pursuant to Section 1301.74(b) upon discovery and before the order is shipped:

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[305] Diversion Investigators Manual, 09/20/2011 (CAH_MDL2804_00953317 at -3396).

[306] Diversion Investigators Manual, 09/20/2011 (CAH_MDL2804 00953317 at -3396).

[307] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[308] May 16, 1984 Letter from Gitchel to NWDA (US-DEA-00026139 at -6150); Seminar Report Controlled Substances Manufacturers and Wholesalers (Apr. 7-9, 1987) (US-DEA-00025656);

- "I want to assure you that DEA fully supports the NWDA effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of after-the-fact sales will not relieve a registrant from responsibility of reporting excessive or suspicious orders. DEA has interpreted 'orders' to mean prior to shipment."[309]

- "Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting these single excessive or suspicious orders. DEA has interpreted 'orders' to mean prior to shipment."[310]

- "Another area of issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment."[311]

- "The submission of a monthly printout of after-the-fact sales does not relieve the registrant of the responsibility of reporting excessive or suspicious orders. These regulations require that a registrant maintain a system to detect excessive 'orders' rather than sales of controlled substances."[312]

- "As you correctly noted, Section 1301.74(b) of Title 21 of the Code of Federal Regulations clearly places the responsibility for designing and operating a system to identify suspicious orders of controlled substances on the registrant. Implicit in this regulation is the idea that the registrant should not merely be accumulating data on what appear to be excessive purchases for eventual submission to DEA but rather that the system be monitored so that any such orders will be apparent to the registrant and so

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Dec. 27, 1988 Letter from Buzzeo to Walgreen Company (US-DEA-00025683); Dec. 8, 1993 Letter from Haislip to Jordan, Dallas Field Division (US-DEA-00026154).

[309] May 16, 1984 Letter from Gitchel to NWDA (US-DEA-00026139 at -6150).

[310] June 21, 1993 NWDA Suspicious Order Monitoring System (US-DEA-00026139 at -6146).

[311] Seminar Report Controlled Substances Manufacturers and Wholesalers Seminar (Apr. 7-9, 1987) (US-DEA-00025656 at -5659).

[312] Dec. 27, 1988 Letter from Buzzeo to Walgreen Company (US-DEA-00025683).

> that they can be reported to DEA upon discovery and, whenever possible, before the order is shipped."[313]

146. Similar to the 1996 Diversion Investigator Manual discussed above, these letters do not refer to or purport to establish the broad "do not ship" policy that would govern orders fall within a particular distributor's parameters for orders of unusual size, unusual frequency, or deviating from a normal pattern. Rather, these documents reminded industry that if a distributor knew or had good reason to believe that an order was destined for the illicit market, then that order should not be shipped and should be reported to DEA.

147. The vast majority of orders that are flagged for meeting the regulatory definition of "suspicious orders," however, are not destined for the illicit market. During my time as a Diversion Investigator, DEA had no expectation that all orders falling within a distributor's parameter for unusual size, unusual frequency, or deviating from a normal pattern would be blocked. And, as stated above, DEA knew that it was "standard practice" in the industry before the Distributor Initiative to report and ship those orders.

148. It would not make sense to interpret these isolated documents as establishing a broad "do not ship" policy. In the 1980s and 1990s, DEA did not train or instruct its Diversion Investigators to apply a broad "do not ship" mandate. In addition, the operative Diversion Investigators Manuals did not include any broad "do not ship" mandate. And, DEA's cyclic audits did not apply any such "do not ship" mandate. If DEA was seeking to adopt a broad "do not ship" policy in this timeframe, then these documents would have been ineffective. It would have been more effective to establish a broad "do not ship" mandate by adopting new regulations

[313] Dec. 8, 1993 Letter from Haislip to Jordan, Dallas Field Division (US-DEA-00026154 at -6154).

or, at a minimum, attempting to communicate the new policy to a wider audience, including industry and personnel in DEA's field offices.

**2. "Know Your Customer" Requirement**

149. As with the "do not ship" requirement, the CSA and the applicable federal regulations do not include DEA's purported new standard for distributors to "know your customer" or to conduct "due diligence" on customers.[314] The diligence requirement is found in § 1301.74(a), which requires registrants to conduct a "good faith inquiry" to determine that a customer holds a valid DEA registration for controlled substances.[315] The 1996 Diversion Investigator Manual further confirms the diligence required under Section 1301.74(a):

> DEA field offices will provide the supplier with the related registration information (i.e., whether the customer is currently registered with DEA) needed to assist the supplier in making an independent decision on whether to ship controlled substances.[316]

150. The 2007 Rannazzisi Letter stated for the first time in an official DEA communication what is now known as the "know your customer" policy.[317] The 2007 Rannazzisi Letter states: "Registrants are reminded that their responsibility does not end merely

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[314] Rannazzisi Tr. (May 15, 2019) at 526:19-24 ("Q. Okay. Now, within the Controlled Substances Act, and in particular those -- those subparagraphs the words "know your customer" does not appear, correct? A. The words 'know your customer' is not in the Controlled Substances Act."); Rannazzisi Tr. (May 15, 2019) at 526:25-528:8; Rannazzisi Tr. (May 15, 2019) at 534:4-21; Prevoznik Tr. (Apr. 17, 2019) at 210:1-10 ("Q. Is there any DEA regulation that says in order for a registrant to make a determination as to whether an order is suspicious or not, they must know their customer to decide? A. It doesn't specifically have that language."); Prevoznik Tr. (Apr. 17, 2019) at 211:7-12; Wright Tr. (Mar. 4, 2019) at 496:3-14; 21 U.S.C. § 823; 21 C.F.R. § 1301.74.

[315] 21 CFR § 1301.74(a); Rafalski Tr. (May 13, 2019) at 385:10-16.

[316] Diversion Investigators Manual, 04/16/1996 (CAH_MDL2804_02203353 at -3356).

[317] Rannazzisi Tr. (May 15, 2019) at 530:7-16 ("Q. Prior to those letters, where are the requirements you spoke of written down somewhere? A. It's -- again, it's part of due diligence. It's not -- it's not written in the Act, but it's part of their due diligence obligations. It's been developed over time. Q. So it's not written in the Act, right? A. It's not in the Act.").

with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."[318]

151. Although these statements in the 2007 Rannazzisi Letter were the first time that DEA had provided these statements in writing to registrants, DEA disclosed some of the concepts to the industry three months earlier at DEA's Pharmaceutical Industry Conference on September 11-12, 2007.[319] There, DEA with AmerisourceBergen explained that "Know Your Customer" Due Diligence investigations [should be] completed on all new Retail and Wholesale Accounts" and "Retail chain pharmacies are exempted."[320] AmerisourceBergen and DEA explained that "[h]istorically Controlled Substance / Listed Chemical order monitoring has been based on a ship and report process," but new processes "[should] now [be] based on: identify, capture, investigate, and report suspicious orders; all **prior to shipment**."[321]

152. As with the purported "do not ship" requirement, the 2011 Diversion Investigators Manual reflects DEA's purportedly new requirement to conduct "know your customer" due diligence:

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[318] December 27, 2007 Dear Registrant Letter (MCKMDL00478910).

[319] Prevoznik Tr. (May 17, 2019) Ex. 29 (DEA Meetings & Events, Pharmaceutical Industry Conference: September 11 & 12, 2007 - Houston, Texas, *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html); Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7188 to -7190).

[320] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7190).

[321] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7192) (emphasis in original).

> Registrants may fill an order that was previously deemed suspicious only after such time as a thorough review has been conducted and findings appropriately documents, as outlined in the Dear Registrant Letter, dated September 27, 2006.[322]

153. The policy as stated here is actually in the December 27, 2007 letter, not the September 27, 2006 letter, but more importantly is not reflected in the CSA or its implementing regulations, as discussed above. This change to DEA policy and guidance occurred after the Distributor Initiative meetings with McKesson.

### 3. DEA Provided Further New Guidance at September 2007 Pharmaceutical Industry Conference in Houston

154. DEA provided industry further new guidance during a September 2007 presentation involving DEA employee Michael Mapes and ABDC's Chris Zimmerman.[323] DEA's new guidance concerned the change for when distributors should report suspicious orders to DEA.

155. During the conference in 2007, DEA and ABDC explained to industry that there was a change concerning when suspicious order reports should be submitted to DEA by distributors.[324] As reflected in the presentation, ABDC at DEA's request explained that "Historically Controlled Substance/Listed Chemical order monitoring has been based on a ***ship and report*** process."[325] At the conference, ABDC at DEA's request explained that "ABC's

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[322] Diversion Investigators Manual, 09/20/2011 (CAH_MDL2804 00953317 at -96).

[323] Prevoznik Tr. (May 17, 2019) at 1159:8-16.

[324] Prevoznik Tr. (May 17, 2019) Ex. 29 (DEA Meetings & Events, Pharmaceutical Industry Conference: September 11 & 12, 2007 - Houston, Texas, *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html).

[325] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7192) (emphasis in original); Prevoznik Tr. (May 17, 2019) at 1163:15-1164:10 ("Q. … [T]his was a presentation that Chris Zimmerman gave at the invitation of the DEA, correct? A. Correct.").

OMP process is now based on: identify, capture, investigate, and report suspicious orders; all ***prior to shipment***."[326] The change in guidance from DEA on when distributors needed to report suspicious orders is reflected in the presentation at DEA's Pharmaceutical Industry Conference in 2007.

### C. DEA's New Guidance During the Distributor Initiative Resulted in Confusion Within the Industry

156. The new requirements that DEA purported to impose on distributors during the Distributor Initiative and with Joseph Rannazzisi's Dear Registrant letters resulted in confusion among the industry.[327] The confusion within industry stemmed in part from the fact that DEA's new requirements represented a shift in standards imposed by DEA.[328] Confusion among industry was also the result of DEA purporting to introduce new standards without changing the relevant regulations or the CSA.[329]

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[326] Chris Zimmerman, Drug Enforcement Administration Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program (Sept. 11, 2007) (ABDCMDL00037184 at -7192) (emphasis in original).

[327] Ashley Tr. (Mar. 15, 2019) at 58:23-59:6 ("Q. At any time during your tenure at the DEA, did you learn that distributors were confused about their suspicious order regulations and wanted more guidance from the DEA? A. I can say in speaking with distributors, they expressed that they wanted more clarification. Q. And so you heard that directly from the distributors? A. Yes.").

[328] Wright Tr. (Feb. 28, 2019) at 120:12-121:3 ("Q. But you did recognize -- and I think your testimony at trial supports this concept -- you recognized that this change from the Excessive Order System to the Suspicious Order System, which was more fluid, would cause confusion in industry, correct? A. Yes. Q. And that was part of the reason you wanted to do these distributor briefings and go one on one with distributors, right? A. Yes. Q. And there was also concern, as I saw from your prior testimony, that your own DEA agents might be confused by the -- the changes going on within the industry, correct?... A. Yes.").

[329] Wright Tr. (Feb. 28, 2019) at 120:12-121:3; Ashley Tr. (Mar. 15, 2019) at 58:23-59:6.

157. Following the new guidance from DEA, distributors reached out to DEA with questions on many occasions.[330] DEA refused to respond to distributor questions on how to implement the new guidance from DEA.[331]

### 1. DEA's Refusal to Provide Guidance Resulted in HDMA Issuing the Industry Compliance Guidelines

158. DEA's policy beginning under Joseph Rannazzisi was to refuse to endorse or approve any registrant's suspicious order monitoring program. In the 2007 Rannazzisi Letter, Mr. Rannazzisi wrote that "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders."[332] In addition to announcing that DEA would no longer approve suspicious order monitoring programs, Mr. Rannazzisi announced in his letter that "Past communications with DEA whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.[333] Mr. Rannazzisi's letter acknowledges that previous explicit and

[330] Questions for the Drug Enforcement Administration (DEA) Regarding Requirements for Suspicious Order Monitoring and Reporting Submitted by the Healthcare Distribution Management Association (June 1, 2011) (US-DEA-00008565); Questions for the Drug Enforcement Administration (DEA) by the Healthcare Distribution Management Association Submitted July 2, 2013 for Discussion on July 31, 2013 (US-DEA-00008577).

[331] Email from L. Milione to D. Ashley, "Fw: Follow-Up from HDA Board Meeting" (US-DEA-00008563).

[332] Dec. 27, 2007 Letter from Joseph Rannazzisi (MCKMDL00478910 at -8910).

[333] Dec. 27, 2007 Letter from Joseph Rannazzisi (MCKMDL00478910 at -8910) (emphasis added).

implicit communications between registrants and DEA constituted approval of suspicious order monitoring systems.[334]

159. DEA's refusal beginning under Mr. Rannazzisi to endorse suspicious monitoring programs or to provide a guidance model contributed to confusion among industry. Distributors now could not receive assurance from DEA that the suspicious order monitoring programs they developed satisfied DEA's new standards.

160. As part of industry's efforts to respond to changes in diversion and new guidance from DEA, the distributors' trade organization, the Healthcare Distribution Management Association, which is commonly known as "HDMA," developed industry guidelines for suspicious order monitoring programs.[335] The guidelines issued by HDMA were voluntary and could be updated to account for the needs of the particular distributor.[336] Again, no changes to the CSA or regulations were made by DEA during this time period.

161. HDMA issued Industry Compliance Guidelines in 2008 that set forth the voluntary guidelines.[337] The 2008 HDMA Industry Compliance Guidelines covered the elements of:

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[334] Dec. 27, 2007 Letter from Joseph Rannazzisi (MCKMDL00478910 at -8910); Wright Tr. (Feb. 28, 2019) at 72:12-16 ("Q. Now, the Excessive Purchase System had been blessed by various DEA offices; is that right? A. Yes, ma'am.").

[335] Healthcare Distribution Management Association Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2008) (MCKMDL00380758); Industry Compliance Guidelines, Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2013) (MCKMDL00380743).

[336] Healthcare Distribution Management Association Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2008) (MCKMDL00380758); Industry Compliance Guidelines, Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2013) (MCKMDL00380743).

[337] Healthcare Distribution Management Association Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2008) (MCKMDL00380758).

- Know Your Customer Due Diligence;
- Monitoring for Suspicious Orders;
- Suspend/Stop an Order of Interest Shipment;
- Investigation of Orders of Interest;
- File Suspicious Order Reports with DEA; and
- Employees, Training, and Standard Operating Procedures.[338]

162. HDMA issued an update to the voluntary guidelines in 2013.[339] The only change from the 2008 version was an update to the preamble in the 2013 version of the guidelines.[340] Industry through HDMA created the voluntary guidelines because DEA refused to approve any specific suspicious order monitoring program and it refused to provide any guidance models to industry.

**2. Criticism of DEA's Failure to Provide Guidance to Industry**

163. DEA was criticized from both inside and outside the agency for its refusal to provide greater guidance to industry. DEA's failure to provide guidance was the subject of a report from the U.S. Government Accountability Office ("GAO") that criticized DEA's responsiveness to industry.[341]

[338] Healthcare Distribution Management Association Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2008) (MCKMDL00380758 at -0760).

[339] Industry Compliance Guidelines, Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2013) (MCKMDL00380743).

[340] Industry Compliance Guidelines, Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (2013) (MCKMDL00380743).

[341] Government Accountability Office, More DEA Information about Registrant's Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access (June 2015) at 44, *available at* https://www.gao.gov/assets/680/671562.pdf.

164. In its 2015 Report, the GAO recommended that DEA "[s]olicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious order monitoring and reporting." GAO also recommended to DEA that "[a] guidance for distributors similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their roles and responsibilities under the CSA for preventing diversion."[342] GAO explained that "although DEA may not be able to provide guidance that will definitively answer the question of what constitutes a suspicious order or offer advice about which customers to ship to, DEA could, for example, provide guidance around best practices in developing suspicious orders monitoring systems."[343] The 2015 GAO report recognized DEA's lack of communication with distributors and recommended ways that DEA could better communicate with distributors.

165. Congressional testimony by DEA's Acting Administrator Chuck Rosenberg confirmed that DEA failed to communicate sufficiently with distributors. Acting Administrator Rosenberg testified to Congress: "And we've been opaque. I think we've been slow. I think we've been opaque. I think we haven't responded to them. We're trying to issue guidelines for them more quickly. We're trying to answer their questions."[344]

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[342] Government Accountability Office, More DEA Information about Registrant's Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access (June 2015) at 27, *available at* https://www.gao.gov/assets/680/671562.pdf.

[343] Government Accountability Office, More DEA Information about Registrant's Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access (June 2015) at 27, *available at* https://www.gao.gov/assets/680/671562.pdf.

[344] Testimony of Chuck Rosenberg, Senate Judiciary Committee Hearing on DEA Oversight (June 22, 2016), *available at* https://plus.cq.com/doc/congressionaltranscripts-4916672?0.

## X. McKesson's Suspicious Order Monitoring Program Changed in Response to Evolving Diversion Trends and Changing DEA Guidance

166. The landscape for pharmaceutical diversion was undergoing charges in light of advancing technology and the rise of rogue Internet pharmacies.[345] Because of these changes in technology and diversion trends, McKesson began to evolve its suspicious order monitoring program.

### A. McKesson's LDMP Program

167. McKesson first developed its Lifestyle Drug Monitoring Program, which is commonly called the "LDMP," in response to changes in guidance from DEA and evolving trends in pharmaceutical diversion.[346] The term "lifestyle drugs" came from DEA and is used in the 2006 Rannazzisi Letter.[347]

#### 1. Overview of McKesson's LDMP Program

168. McKesson adopted its LDMP program in May 2007.[348] In light of McKesson's discussions with DEA about rogue Internet pharmacies, the LDMP focused on the unprecedented threat from rogue Internet pharmacies.[349] The LDMP calls for monitoring of four specific drugs:

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[345] Prevoznik Tr. (Apr.17, 2019) at 151:1-17 ("A. … It's with the onset of the internet where it became national. So it really changed the dynamic of diversion when it went on the internet."); Prevoznik Tr. (Apr. 17, 2019) at 298:2-17 ("Back in 2005 when we started, that was when we were addressing the internet. So it went from the regional local diversion issues to a more national – not a more – I mean it went national.").

[346] Walker Tr. (Jan. 10, 2019) at 374:7-12 ("A. We – this was really the beginning of our overall control of the monitoring program. We focused on the four lifestyle drugs that had been identified in the January meeting. We established a mechanism of thresholds DEA had shared with U.S. in the – in the meetings that we had had ….").

[347] September 27, 2006 Dear Registrant Letter (MCKMDL00478906 at -8908) ("Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.").

[348] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5256).

[349] Boggs Tr. (Jan. 17, 2019) at 102:3-15 ("Q. Before creating the CSMP as a result of this settlement agreement, did McKesson have what is referred to as a Lifestyle Drug Monitoring

oxycodone, hydrocodone, alprazolam, and phentermine.[350] To respond to this diversion trend, the LDMP sets monthly thresholds for oxycodone, hydrocodone, alprazolam, and phentermine. The LDMP set thresholds for those four drugs at 8,000 doses.[351]

169. The LDMP created a three-level monitoring program.[352] Under the three-level system, McKesson would review a customer's orders greater than the 8,000 dose threshold.[353] McKesson's LDMP program generated a Daily Dosage Summary Report.[354] The Daily Dosage Summary Report summarized all McKesson's customers who purchased amounts of oxycodone, hydrocodone, alprazolam, or phentermine that exceeded the 8,000 dose unit threshold set for those products in that month.[355] McKesson employees then reviewed whether the customer orders that appeared on the Daily Dosage Summary Report were legitimate.[356]

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Program? A. That's my understanding, yes. Q. And in that context, lifestyle drugs referred to what? … THE WITNESS: From -- from reading the documents, it referred to drugs that they had discussed with the DEA regarding drugs that were used pursuant to a rogue internet pharmacy.").

[350] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251); Boggs Tr. (Jan. 17, 2019) at 102:3-15 ("Q. Before creating the CSMP as a result of this settlement agreement, did McKesson have what is referred to as a Lifestyle Drug Monitoring Program? A. That's my understanding, yes. Q. And in that context, lifestyle drugs referred to what? … THE WITNESS: From – from reading the documents, it referred to drugs that they had discussed with the DEA regarding drugs that were used pursuant to a rogue internet pharmacy."); Walker Tr. (Jan. 10, 2019) at 374:7-10 ("A. … We focused on the four lifestyle drugs that had been identified in the January meeting.").

[351] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251).

[352] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5252-55); Walker Tr. (Jan. 10, 2019) at 374:2-375:10.

[353] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251); Walker Tr. (Jan. 10, 2019) at 374:7-19 ("A. … "Our own internal data we reviewed, it was -- the average was closer to 8,000 dose units for our customer base. And we then used the information, the data, to establish these thresholds.").

[354] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251).

[355] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251).

[356] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251).

170. The LDMP did not automatically block orders of oxycodone, hydrocodone, alprazolam, or phentermine that exceeded the 8,000 dose threshold.[357] McKesson employees, however, were required to investigate customer activity when the 8,000 dose threshold of those four drugs was reached.[358]

### 2. McKesson's Section 55 Program Remained in Effect for Other Controlled Substances

171. As I discuss above, McKesson's LDMP monitored four specific controlled substances, which were oxycodone, hydrocodone, alprazolam, and phentermine.[359] For other controlled substances, reporting under McKesson's Section 55 program remained in effect.[360]

### 3. McKesson Reported DU-45s During the LDMP Program

172. McKesson continued to submit DU-45 reports to DEA while its LDMP program was in effect.[361] The LDMP program did not stop McKesson's reporting of suspicious orders to

[357] Lifestyle Drug Monitoring Program (MCKMDL00355251); William de Gutierrez-Mahoney Tr. (Nov. 28, 2018) at 576:3-15 ("Q. The LDMP didn't block suspicious orders, did it? A. It identified them so we could instruct the nightshift don't fill decisional hydrocodone for a specific customer. Q. When orders exceeded their thresholds under the LDMP, they weren't blocked, were they? A. It was -- there wasn't a threshold, per se. But there was a designated level above which we would do the investigation.").

[358] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251) ("Each customer appearing on the report must be evaluated to the legitimacy of their order quantity.").

[359] Lifestyle Drug Monitoring Program (MCKMDL00355251 at -5251).

[360] Walker Tr. (Jan. 10, 2019) at 384:12-22 ("Q. What is this? A. This is a memo from -- or an email memo from me to our field distribution teams and distribution centers advising them that -- this is dated January 22nd of '09 – that we would no longer be providing the DEA with the end-of-month DU45 or the Suspicious Order Report, and that our new reporting mechanism was in place and established as part of our agreement with DEA, and directed the DCs not to submit those reports to the local field offices.").

[361] Walker Tr. (Jan. 10, 2019) at 383:8-9 ("A. We – we continued to submit the DU45 9 to local field offices.").

DEA through DU-45s.[362] McKesson only stopped sending DU-45 reports to DEA in January 2009 at the request of DEA.[363]

#### 4. McKesson Informed DEA of the LDMP and DEA Did Not Raise Concerns About the Program

173. McKesson provided DEA with the LDMP policy and a presentation that summarized key aspects of the LDMP program.[364] At the time, Linden Barber was Chief of the Regulatory Section in DEA's Office of Chief Counsel, and he received the information about the LDMP program from McKesson.[365] DEA understood McKesson's LDMP program and that McKesson did not block orders of the four controlled substances that exceeded the 8,000 dose threshold for the month.[366]

#### 5. McKesson's LDMP Program Complied with the CSA and Regulations

174. It is my opinion that McKesson's LDMP program complied with the requirements of the CSA, its regulations, and DEA's guidance. The LDMP program identified suspicious orders and McKesson investigated orders that exceeded the threshold for those four controlled

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[362] Walker Tr. (Jan. 10, 2019) at 383:8-9 ("A. We – we continued to submit the DU45 9 to local field offices.").

[363] Walker Tr. (Jan. 10, 2019) at 383:20-384:2 ("Q. … When did McKesson cease providing DU45 reports to the DEA? A. I think in January of '09, we finally reached mutual agreement that we had a system that could talk back and forth. And I think in January of 2009 is when we ceased providing DU45s."); Email from Donald Walker, "IMPORTANT – Call from DEA on Suspicious Trans Rpt" (Jan. 22, 2009) (MCKMDL00355691 at -5691) ("They received paper suspicious transaction reports (DU45) from St. Louis and Birmingham and are questioning why we are still sending paper reports."); Email from Donald Walker, "DU45" (Jan. 22, 2009) (MCKMDL00355693 at -5693) ("Effective this month we will no longer be providing DEA with the end of month DU45.").

[364] Letter from John Gilbert to Linden Barber (June 12, 2007) (MCKMDL00355527 at -5527-28).

[365] Letter from John Gilbert to Linden Barber (June 12, 2007) (MCKMDL00355527 at -5527-28).

[366] Letter from John Gilbert to Linden Barber (June 12, 2007) (MCKMDL00355527 at -5527-28).

substances. McKesson also reported suspicious orders to DEA using DU-45s.[367] It is also important to remember that McKesson continued to use its Section 55 Program for other controlled substances during the LDMP program.

**B. McKesson's 2008 Controlled Substance Monitoring Program**

175. During McKesson's LDMP program, trends in pharmaceutical diversion continued to change. Congress passed the Ryan Haight Act in 2008, and after the Act took effect, rogue Internet pharmacies became virtually nonexistent.[368] As rogue Internet pharmacies decreased, a new diversion scheme emerged.[369]

176. The diversion trend that emerged by the late 2000s was rogue pain clinics or "pill mills."[370] The pill mill diversion scheme involved brick-and-mortar pharmacies that filled high

[367] Walker Tr. (Jan. 10, 2019) at 384:13-22 ("A. This is a memo from -- or an email memo from me to our field distribution teams and distribution centers advising them that -- this is dated January 22nd of '09 -- that we would no longer be providing the DEA with the end-of-month DU45 or the Suspicious order report, and that our new reporting mechanism was in place and established as part of our agreement with DEA, and directed the DCs not to submit those reports to the local field offices.").

[368] Boggs Tr. (Jan. 17, 2019) at 82:21-83:1 ("A. … Most of these are focused predominantly on -- on what would be a rogue internet pharmacy, which in today's environment is almost nonexistent.").

[369] Boggs Tr. (Jan. 17, 2019) at 356:14-22 (Q And can you describe, what is a diversion trend? A. There's different types of schemes that can occur that would cause a -- what I would consider a trend. We've -- we've seen diversion trends, such as rogue internet pharmacies, be a diversion trend. It's a massive criminal scheme. We've seen pill mills in Florida. That's a diversion trend and is a criminal scheme.").

[370] Boggs Tr. (Jan. 17, 2019) at 137:5-13 ("Q. On page 897, you reference 'Florida pill mills, resulting oxy spills.' Was there a particular problem in Florida in the late 2000s, including 2009 and 2010, as it related to large quantities of opioids being diverted into the illicit marketplace? A. There was a significant diversion scheme related to pain -- rogue pain clinics or what were often referred to as pill mills."); Boggs Tr. (Jan. 17, 2019) at 141:14-17 ("A. The bullets that are in here are focused specifically on a diversion scheme, and in this case it would have been a pill mill or rogue pain clinic."); Boggs Tr. (July 19, 2018) at 90:19-25 ("Q. What do the arrows signify to you? A. I believe it would be in reference to the Florida fill mills and oxycodone traveling out of the state of Florida being diverted by illegal trafficking.").

volumes of controlled substances that lacked legitimate medical purposes. These were criminal enterprises in which a patient would come in, see a doctor, get a prescription for which there was no legitimate medical need, and then have the prescription filled at the pharmacy for a cash payment.

177. McKesson adapted its anti-diversion program to keep pace with changing diversion trends resulting in shifting DEA guidance such as "Do Not Ship." McKesson adopted its Controlled Substances Monitoring Program, which I will call the "2008 CSMP," in April 2008 to address these changes.

**1. Overview of McKesson's 2008 CSMP**

178. McKesson's 2008 CSMP took effect in April 2008.[371] The 2008 CSMP applied to all controlled substances.[372] The 2008 CSMP was not limited to the four pharmaceutical products identified in the LDMP.[373]

**2. 2008 CSMP Blocked Orders That Met or Exceeded the Monthly Threshold**

179. McKesson's 2008 CSMP established individualized customer thresholds for all controlled substances using DEA base code.[374] When a customer hit its monthly threshold for a

[371] McKesson Pharmaceutical Controlled Substance Monitoring Program (CSMP), Presentation (July 31, 2008) (MCKMDL00355595 at -5599); Walker Tr. (Jan. 10, 2019) at 242:17-21 ("Q. And it's April 24, 2008. This is about the time that you're beginning the implementation of the monitoring program at McKesson; true? A. Yes, we were implementing.").

[372] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9301).

[373] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9301).

[374] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9302); Walker Tr. (Jan. 10, 2019) at 381:8-18 ("Q. What was the difference between the new CSMP program that was put into place and the LDMP, or Lifestyle Drug Monitoring Program? A. There were a number of things that -- that were done at the time. First, the difference specifically in the programs is we continued to use the concept of thresholds to monitor specific orders. The significant difference was that we created a systemic solution to total the dose units purchased by a given pharmacy on a given controlled substances -- substance.").

particular controlled substance, the automatic "do not ship" was triggered.[375] The order, which was referred to within McKesson as an "omit," was blocked, and McKesson did not ship the order.[376] When a customer hit its threshold, the order that triggered the omit was blocked, and McKesson blocked all subsequent orders for that item from that customer.[377]

### 3. 2008 CSMP Three-Level Review Process

180. When a customer's order met or exceeded the threshold under the 2008 CSMP, it also triggered McKesson's three-level review process.[378] McKesson's 2008 CSMP required a Level I review every time a customer hit its monthly threshold.[379]

181. If McKesson determined during the Level I review that additional investigation was warranted, McKesson would open a Level II review.[380] A Level II review involved coordination between the Distribution Center and a Director of Regulatory Affairs.[381] The review could also involve customer interviews and site visits.[382] When a Level II review was

[375] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9306); Walker Tr. (Jan. 10, 2019) at 381:11-21 ("A. … And if the order that was generated at any given time caused the pharmacy to go above the threshold, that entire order was blocked. The blocking of orders was a piece.").

[376] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9306).

[377] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9306); Walker Tr. (Jan. 10, 2019) at 381:11-21 ("A. … And if the order that was generated at any given time caused the pharmacy to go above the threshold, that entire order was blocked. The blocking of orders was a piece.").

[378] Walker Tr. (Jan. 10, 2019) at 381:11-382:1 ("A. … We had -- we continued to have the three-part review. The difference being is that the blocked order triggered a review process, but we still maintained a three-tiered escalation process and how we would report to the DEA.").

[379] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9306-07).

[380] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9307).

[381] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9307).

[382] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9307).

completed, the customer was escalated to Level III review if the transaction was determined to be "suspicious."[383]

182. Once an evaluation is escalated to a Level III, sales of all controlled substances are blocked to the customer.[384] McKesson also reports the customer to local and headquarters DEA personnel as "suspicious."[385] Level III reviews are handled by senior management at McKesson.[386]

#### 4. "Know Your Customer" Under the 2008 CSMP

183. The 2008 CSMP states that "DEA expects McKesson to 'know their customer.' This means understanding the customers' business, why they purchase as well as how much they purchase. Factors such as type of business, internet activities, type and quantity of products purchased should be considered when evaluating a customer."[387] McKesson took steps to know both its new and established customers.

##### a) "Know Your Customer" for New Customers

184. McKesson's 2008 CSMP had procedures to make sure that potential customers satisfied McKesson's onboarding requirements.[388] For example, McKesson introduced new customers to the CSMP process.[389] McKesson also conducted site visits during the onboarding process for new customers.[390]

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[383] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9308).
[384] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9308).
[385] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9308).
[386] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9308).
[387] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9301).
[388] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9308).
[389] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9308-09).
[390] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9312).

**b) "Know Your Customer" for Existing Customers**

185. McKesson under the 2008 CSMP conducted due diligence to "know its customers" for existing customers as well.[391] McKesson's due diligence involved a number of steps, such as a customer declaration, site visit, observations, follow-up interviews, inquiries with local DEA or the state board of pharmacy, Internet searches, and extensive background investigations by corporate security.[392]

**5. McKesson Reported DU-45s until January 2009**

186. McKesson continued certain elements of its earlier controlled substance monitoring programs during the 2008 CSMP. McKesson, for example, continued to submit DU-45 reports to DEA through January 2009.[393] McKesson stopped submitting DU-45s to DEA in 2009 because McKesson's new method of reporting to DEA took effect.[394] DEA also informed industry in 2010 in a presentation that DEA would no longer accept excessive purchase reports.[395] McKesson continued to maintain regular contact with their local field offices under the 2008 CSMP.[396]

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[391] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9313).

[392] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9313).

[393] Walker Tr. (Jan. 10, 2019) at 383:20-384:2 ("Q. And you mentioned that the DU45s were continued -- McKesson continued to send those while the new system was in development. When did McKesson cease providing DU45 reports to the DEA? A. I think in January of '09, we finally reached mutual agreement that we had a system that could talk back and forth. And I think in January of 2009 is when we ceased providing DU45.").

[394] Email from Donald Walker, "DU45," (Jan. 22, 2009) (MCKMDL00355693 at -5693) ("Our new reporting mechanism established as part of the agreement with DEA is now in place and verified operational.").

[395] Regulatory Section, DEA Headquarters, ODG Presentation (CAH_MDL2804_01447421 at -7435) ("DEA will no longer accept Excessive Purchase Reports. Previously excessive purchase reports were received after drugs had already been shipped by registrants.").

[396] Thomas McDonald Tr. (Dec. 7, 2018) at 296:6-297:25 ("A. When I first started as Director, I wanted to reach out to local DEA offices in my territory and present CSMP. So once I became

### 6. McKesson's 2008 CSMP Complied with the CSA and Regulations

187. McKesson's 2008 CSMP complied with the requirements under the CSA and its regulations. McKesson implemented its 2008 CSMP in conjunction with DEA and in a way that was consistent with DEA's guidance under the 2008 Settlement Agreement.[397] The 2008 CSMP

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comfortable with the process, I would try to schedule appointments with local offices so that I could make that presentation, make liaison with those offices, and try to open communication with them. … Q. And as to the group supervisors or diversion managers that were receptive, could you describe your interactions with them? A. Often I would -- I would contact them, and if I was doing an investigation, and ask them if they had heard of a particular pharmacy or heard of a doctor in the area that was mentioned during an investigation.").

[397] McKesson Corporation, Presentation to the U.S. Attorney's Office, Northern District of West Virginia and DEA (Mar. 12, 2014) (MCKMDL00409116 at -9133) ("June 2008: McKesson and DEA representatives began discussing development of electronic reporting system, November 4, 2008: DEA provided detail on electronic reporting format for Suspicious Orders and Non-ARCOS data, January 22, 2009: McKesson discontinued DU-45 in consultation with DEA."); (MCKMDL00409116 at -9151) ("DEA determined McKesson's DC's were 'satisfactory' per the MOA."); (MCKMDL00409116 at -9161) ("July - December 2009: McKesson coordinated with DEA on the continued development of the electronic reporting system … May 14-25, 2010: McKesson and DEA jointly tested the process for electronically reporting suspicious orders."); Walker Tr. (Jan. 10, 2019) at 141:16-21 ("Q. And the program you actually established in '08 was consistent with that agreement? Because what we just went through, when we look at your program under 'Purpose,' it says you're going to set and maintain thresholds; right? A. Yes."); Oriente Tr. (July 19, 2018) at 363:8-19 ("Q. And in 2008, after paying $13 million -- a $13 million fine with respect to your settlement with the DOJ and the DEA, at that point in time you agreed, you agreed with the DEA that you would establish a system with thresholds to monitor the flow of opioids, did you not, sir? … THE WITNESS: I believe that was the -- a statement made."); Boggs Tr. (Jan. 17, 2019) at 61:3-15 ("Q. As a result of this settlement, McKesson agreed to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA, the Controlled Substances Act, and applicable DEA regulations, and then it goes on to indicate that McKesson would establish thresholds for controlled substances. Is it your understanding that that was part of the obligations assumed by McKesson as a result of the settlement? A. That's what it says on the document, yes."); Boggs Tr. (July 19, 2018) at 58:21-25 ("Q. In addition, McKesson agreed to institute a compliance program to detect and prevent diversion of controlled substances? A. That was part of the agreement, yes."); Boggs Tr. (July 19, 2019) at 59:22-60:4 ("Q. What were the general terms or provisions of the compliance addendum in 2008? A. There was an agreement to maintain effective controls against diversion, a controlled substances monitoring program, and it outlines that agree -- in the agreement."); Walker Tr. (Jan. 10, 2019) at 382:9-383:2 ("Q. … What actions did McKesson take to implement those provisions [of the 2008 agreement], specifically dealing with suspicious order reporting? A. … So we had a fairly significant I.T. team and I.T. investment to execute the establishment of the suspicious or recording mechanism to report to DEA.").

was designed and implemented to combat diversion as it existed during this time, which was mainly rogue Internet pharmacies and pill mills.

### C. McKesson's Enhanced Controlled Substance Monitoring Program from 2013 to Present

188. McKesson continued to develop and enhance its controlled substance monitoring program to address changes in diversion trends and changes in the business practices of McKesson's customers.[398] At the beginning of this decade, diversion trends shifted from rogue Internet pharmacies and pill mills to high volume brick-and-mortar pharmacies.[399] McKesson developed its Enhanced CSMP to better address such changes in pharmaceutical diversion.

#### 1. Advancements Incorporated into McKesson's Enhanced CSMP

189. McKesson's Enhanced CSMP included advancements that McKesson adopted to address shifts in pharmaceutical diversion. McKesson hired several high-caliber former DEA personnel with expertise in fast-moving diversion trends as part of its efforts to address diversion.[400] McKesson hired these experienced individuals so that McKesson could rely on their experience combatting diversion in its suspicious order monitoring program.[401]

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[398] 2013 Controlled Substances Monitoring Program (MCKMDL00354536 at -4536).

[399] Boggs Tr. (Jan. 17, 2019) at 356:14-357:23 ("Q. And can you describe, what is a diversion trend? A. … [W]e've seen diversion trends, such as rogue internet pharmacies, be a diversion. It's a massive criminal scheme. We've seen pill mills in Florida. That's a diversion trend and is a criminal scheme.").

[400] McKesson Corporation, Presentation to the U.S. Attorney's Office, Northern District of West Virginia and DEA (Mar. 12, 2014) (MCKMDL00409116 at -9168).

[401] Boggs Tr. (Jan. 17, 2019) at 47:22-48:8 ("Q. Did you bring with you when you joined McKesson your wealth of knowledge that you gained as a DEA agent, and do you use that knowledge in your current position and employment? A. I use my experiences gained from there, yes. Q. I assume that's why McKesson retained you, for your knowledge and experience as a DEA agent. True? A. I think that that's partially accurate, yes."); Boggs Tr. (Jan. 17, 2019) at 206:2-8 ("Q. The next thing you mention is a larger and experienced regulatory team. What does that mean? A. We expanded the number of people on our team. We brought in different experience, expertise and skill sets to our team as we evolved our program."); Boggs Tr. (Jan.

190. McKesson also incorporated advancements into its Enhanced CSMP. Under the Enhanced CSMP, McKesson:

- Used detailed analytical tools to evaluate customers' thresholds;[402]
- Reviewed and reset its customers' thresholds;[403]
- Reviewed and revised factors for adjusting customers' thresholds; and[404]
- Refined suspicious order reporting.[405]

**2. Separate Policies for Retail Accounts and Independent Customers Beginning in 2015**

191. McKesson released a CSMP policy focused on independent, small, to medium chain ("ISMC") customers in 2015.[406] McKesson also released a CSMP focused on retail national account ("RNA") customers in 2018.[407] Both the RNA and ISMC versions of

17, 2019) at 387:6-21 ("Q. Mr. Boggs, how many other former DEA representatives or agents are now employed at McKesson besides yourself, if you can estimate? A. About six or seven. Q. Does that include former DEA attorneys as well as agents? A. It did not, but there -- we -- there's one. Q. Just one. And before 2013, do you know whether any DEA agents were employed at McKesson, former DEA agents? A. There's a -- was a diversion investigator, not a DEA agent, that was employed by -- Q. Just one? A. -- prior to my arrival, yes.").

[402] McKesson Corporation, Presentation to the U.S. Attorney's Office, Northern District of West Virginia and DEA (Mar. 12, 2014) (MCKMDL00409116, at -9168); AGI, Suspicious Order Monitoring Threshold System for McKesson Independent Retail Pharmacy Customers, Description and Rationale (May 12, 2017) (MCKMDL00409766).

[403] McKesson Corporation, Presentation to the U.S. Attorney's Office, Northern District of West Virginia and DEA (Mar. 12, 2014) (MCKMDL00409116 at -9168).

[404] McKesson Corporation, Presentation to the U.S. Attorney's Office, Northern District of West Virginia and DEA (Mar. 12, 2014) (MCKMDL00409116 at -9168).

[405] McKesson Corporation, Presentation to the U.S. Attorney's Office, Northern District of West Virginia and DEA (Mar. 12, 2014) (MCKMDL00409116 at -9168).

[406] 2015 ISMC Controlled Substance Monitoring Program Operating Manual (MCKMDL00354887).

[407] 2018 RNA Controlled Substance Monitoring Program Operating Manual (MCKMDL00355260).

McKesson's Enhanced CSMP provide guidance on diligence practices, threshold changes, and customer onboarding procedures that are specific to that type of customer.[408]

192. McKesson's Enhanced CSMP involved the adoption of an advanced threshold system developed by the Analysis Group ("AGI"). McKesson invested significant resources to build and maintain analytical tools, such as Solver and the AGI dynamic threshold model, in recognition of the new demands being placed on distributors. Working with AGI, McKesson developed improved statistical models and algorithms to establish and manage thresholds for McKesson's customers.[409]

**3. McKesson's Use of Red Flags**

193. As part of its Enhanced CSMP, McKesson identified a list of statistical and non-statistical red flags in its CSMP.[410] This was not the first time that McKesson paid attention to items on this list, which were used as potential indicators of diversion.[411]

**4. Plaintiffs' Expert Supports McKesson's Enhanced CSMP**

194. James Rafalski, who I understand that Plaintiffs offer as a suspicious order monitoring program expert, recognized at his deposition positive attributes of McKesson's Enchanced CSMP program incorporating AGI. He stated that "I thought that … had the

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[408] 2018 RNA Controlled Substance Monitoring Program Operating Manual (MCKMDL00355260).

[409] Boggs Tr. (Jan. 17, 2019) at 85:13-87:1.

[410] 2015 ISMC Controlled Substance Monitoring Program Operating Manual, (MCKMDL00330099 at -3116-20). [redacted]

[411] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9311-9313).

potential for a good system."[412] Mr. Rafalski also testified that "they were making some changes to their suspicious order monitoring system that I thought were pretty positive and significant, but it was right at the very end of the timeline. That was one company. That would have been McKesson."[413]

#### 5. McKesson's Enhanced CSMP Complied with the CSA and Regulations

195. The Enhanced CSMP developed by McKesson complies with the requirements in the CSA and its regulations. In fact, McKesson's Enhanced CSMP and its program with AGI go beyond the requirements of the CSA and regulations and are highly sophisticated programs designed to combat pharmaceutical diversion. And throughout this process, DEA never modified the CSA and its regulations.

## XI. McKesson Settlement Agreements

196. McKesson has been subject to two administrative settlements with DEA. McKesson entered into a first settlement agreement with DEA in 2008[414] and a second settlement agreement with DEA in 2017.[415]

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[412] Rafalski Tr. (May 13, 2019) at 353:25-354:12 ("Q. What positive things did you see in McKesson's suspicious order monitoring program? A. At the very end of the time period, they contracted or -- a company called AGI, and AGI did a -- was designing a model for them, and I thought just by looking what limited information I got, that I thought there was some potential for that. I'm not saying that I'm approving it, and without actually doing a lot more analysis, but I thought that that was -- had the potential for a good system.").

[413] Rafalski Tr. (May 13, 2019) at 38:11-16.

[414] 2008 Settlement Agreement (MCKMDL00516360).

[415] 2017 Agreement and Release (MCKMDL00410006); 2017 Memorandum of Agreement (MCKMDL00410070).

### A. 2008 Settlement Agreement

197. McKesson entered a Settlement and Release Agreement and Administrative Memorandum of Agreement with the Department of Justice, Drug Enforcement Administration on May 2, 2008 (the "2008 Settlement Agreement").[416] The 2008 Settlement Agreement resulted from Orders to Show Cause dated August 4, 2006, and November 1, 2007.[417]

198. Among other obligations under the 2008 Settlement Agreement, McKesson agreed to pay civil penalties in the amount of $13.25 million.[418] However, as stated in the 2008 Settlement Agreement, "McKesson denies the allegations set forth in the Orders and as otherwise summarized above and also denies any allegations of improper conduct including but not limited to allegations that it failed to maintain effective controls against diversion or failed to file suspicious order reports."[419]

199. I further understand that DEA did not issue an Immediate Suspension Order against McKesson for any of the alleged conduct described in the 2008 Settlement Agreement.[420] This is significant because DEA concluded that McKesson's alleged conduct did not amount to "an imminent danger to the public health or safety."[421]

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[416] 2008 Settlement Agreement (MCKMDL00516360).

[417] 2008 Settlement Agreement (MCKMDL00516360 at -6360, -6361).

[418] 2008 Settlement Agreement (MCKMDL00516360 at -6364).

[419] 2008 Settlement Agreement (MCKMDL00516360 at -6361).

[420] Rannazzisi Tr. (May 15, 2019) at 593:6-11.

[421] 21 C.F.R. § 1301.36(e) ("The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he/she finds that there is an imminent danger to the public health or safety.").

### B. 2017 Settlement Agreement

200. McKesson entered a Settlement Agreement and Release on January 17, 2017 (the "2017 Settlement Agreement").[422] The 2017 Settlement Agreement does not recite an Order to Show Cause or other administrative proceeding, but McKesson agreed to pay civil penalties in the amount of $150 million, among other obligations.[423] McKesson also agreed to enter a Compliance Addendum and Administrative Memorandum of Agreement under which its authority to distribute certain controlled substances from four of its distribution centers would be suspended for a period of up to 3 years.[424]

201. McKesson further agreed that it did not identify or report "certain orders placed by certain pharmacies which should have been detected based on guidance contained in DEA letters."[425] McKesson further admitted it did not report "certain orders placed by certain pharmacies" in a manner consistent with 2008 Settlement Agreement.[426] As with the 2008 Settlement Agreement, I understand that DEA did not issue an Immediate Suspension Order

[422] 2017 Agreement and Release (MCKMDL00410006); 2017 Memorandum of Agreement (MCKMDL00410070).

[423] 2017 Agreement and Release (MCKMDL00410006 at -0011); 2017 Memorandum of Agreement (MCKMDL00410070 at -0077).

[424] 2017 Memorandum of Agreement (MCKMDL00410070 at -0075-77).

[425] 2017 Agreement and Release (MCKMDL00410006 at -0010) ("McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.SC. § 842(a)(5).").

[426] 2017 Agreement and Release (MCKMDL00410006 at -0010) ("McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.").

against McKesson for any of the alleged conduct described in the 2017 Settlement Agreement.[427] Again, this is significant because DEA concluded that McKesson's alleged conduct did not amount to "an imminent danger to the public health or safety."[428]

202. Although McKesson admitted it did not report "certain orders placed by certain pharmacies," it is important to note that the 2017 Settlement Agreement covered conduct from January 1, 2009 through January 17, 2017.[429] As discussed above, during this period McKesson blocked suspicious orders before they were shipped under its CSMP program.[430] Mr. Rafalski has explained that "[t]here is no more effective control to prevent diversion than blocking a suspicious order before it is shipped."[431] This is because the order "doesn't leave the control of the distributor and have the potential to be diverted."[432] Mr. Rafalski testified that "not reporting

[427] Rannazzisi Tr. (May 15, 2019) at 593:6-17 ("Q. … Sitting here today, you don't recall if the DEA issued an immediate suspension order against McKesson during your tenure at the DEA, correct? A. I don't recall that.").

[428] 21 C.F.R. § 1301.36(e) ("The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he/she finds that there is an imminent danger to the public health or safety.").

[429] 2017 Agreement and Release (MCKMDL00410006 at -0007-08); 2017 Memorandum of Agreement (MCKMDL00410070 at -0072).

[430] McKesson Controlled Substance Monitoring Program (MCKMDL00409301 at -9306); Boggs Tr. (Jan. 17, 2019) at 366:4-7 ("Q. … [I]f it triggered a suspicious order, that order would be blocked, it would not be shipped, and that order would be reported to the DEA."), 378:3-9 ("Q. [D]o you believe that the failure to report contributed to the opioid crisis? A. I don't, because the order may very well have been blocked and not shipped. It doesn't mean it was reported or not reported, but the order may have been blocked, and McKesson was blocking orders for quite some time.").

[431] Expert Report of James E. Rafalski (Apr. 15, 2019) at 74; Rafalski Tr. (May 13, 2019) 370:25-371:3 ("Q. Blocking the order of the opioid pills before shipment is what prevents diversion from occurring, correct? A. Yes, sir.").

[432] Rafalski Tr. (May 13, 2019) at 370:25-371:3 (agreeing that "[b]locking the order of the opioid pills before shipment is what prevents diversion from occurring").

the suspicious order to DEA is not what causes diversion."[433] I have not seen any suggestion that the orders subject to the 2017 Settlement Agreement caused diversion.

## XII. DEA Rarely Relied On or Used Suspicious Order Reports

### A. DEA Rarely Used Suspicious Order Reports

203. During my time as a Diversion Investigator, suspicious order reports were not typically used by DEA to detect suspicious orders or to identify diversion. Diversion investigators typically did not rely on suspicious order reports while they were looking for sources of diversion. In my experience, suspicious order reports were not a priority of DEA field offices. In addition, suspicious order reports were not typically among the tools used by diversion investigators when conducting investigations of pharmacies suspected of diversion. DEA did not typically use suspicious order reports as a springboard to conduct investigations of pharmacies in my experience.[434]

204. My experience at DEA was confirmed by testimony from DEA witnesses. DEA admitted that suspicious order reports were not consistently maintained by DEA field offices.[435] Former DEA employee Kyle Wright also testified on multiple occasions that fifty to seventy-five

[433] Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. You'd agree that not reporting the suspicious order to DEA is not what causes diversion? A. That's correct.").

[434] Wright Tr. (Feb. 28, 2019) at 84:9-21 ("Q. And I believe that you testified before, in your personal experience reviewing these Excessive Sales Reports, that half to three-quarters of them sometimes went into the trash can; is that right? A. Yes."); Wright Tr. (US v. $463,497.72) at 47:8-49:5 ("Q. It won't just be filed away in a drawer? A. That was the problem with the Excessive Purchase System. It was under the Suspicious Order System. Q. Whose fault was that? Is that the distributor's fault or the DEA's fault? A. That would have been the DEA's fault. Well, no. Let me -- let me reel some of that back in. … I would look through -- again, I had a ton of paper, and I would say half to three-quarters of that went in the trash can. It was meaningless. … Q. You're not suggesting that H.D. Smith was dumping paper on the DEA? A. No, sir. No, sir. No, sir. Not at all. Q. Okay. A. I would just get a volume of paper.").

[435] Prevoznik Tr. (Apr. 17, 2019) at 383:9-12 ("Q. So in DEA's view, were suspicious order reports maintained consistently across the field offices? A. No.").

percent of the excessive order reports submitted by distributors to DEA ended up in the trash.[436] Kyle Wright described the reports as "meaningless."[437] Gary Boggs testified that suspicious order reports are "rarely" useful in identifying and investigating suspicious orders, and the focus on suspicious orders is "very misplaced."[438] He also testified that the suspicious order reports that he receives while working at McKesson are not a useful tool for detecting potential diversion.[439]

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[436] Wright Tr. (Feb. 28, 2019) at 84:9-21 ("Q. And I believe that you testified before, in your personal experience reviewing these Excessive Sales Reports, that half to three-quarters of them sometimes went into the trash can; is that right? A. Yes."); Wright Tr. (US v. $463,497.72) at 47:8-49:5 ("Q. It won't just be filed away in a drawer? A. That was the problem with the Excessive Purchase System. It was under the Suspicious Order System. Q. Whose fault was that? Is that the distributor's fault or the DEA's fault? A. That would have been the DEA's fault. Well, no. Let me -- let me reel some of that back in. … I would look through -- again, I had a ton of paper, and I would say half to three-quarters of that went in the trash can. It was meaningless. … Q. You're not suggesting that H.D. Smith was dumping paper on the DEA? A. No, sir. No, sir. No, sir. Not at all. Q. Okay. A. I would just get a volume of paper.").

[437] Wright Tr. (US v. $463,497.72) at 47:12-22 ("A. … I had a ton of paper, and I would say half to three-quarters of that went in the trash can. It was meaningless. …").

[438] Boggs Tr. (Jan. 17, 2019) at 97:14-98:2 ("Q. … Suspicious orders can lead you to a suspicious customer, true? … A. Without knowing more about the customer, no."), Boggs Tr. (Jan. 17, 2019) 368:1-369:7 ("Q. Why do you look at the [suspicious order] reports? A. To see if there's anything in there that I should be concerned about, or if there's anything -- if a customer ordered an extremely large volume of something that would have been a -- not a typical order, I would be able to see that, and maybe decide that someone from our team needed to do some additional due diligence. Q. How often do you look at a suspicious order report and make a determination that something -- some additional diligence is warranted? A. I look at them probably every day, every other day. I mean, I look at them very frequently, but rarely do I find anything that -- of concern in those.")

[439] Boggs Tr. (Jan. 17, 2019) at 368:17-369:7 ("Q. Does that mean that you rarely have concerns about your customers, or -- is that what you're saying, you rarely have concerns about your customers? A. No, it means that rarely do I find any of those orders to be concerning. We do other due diligence of our customers that that due diligence -- because we're looking and knowing our customer and conducting the due diligence of our customer, that we find additional red flags that are not borne out in a suspicious order report. Q. So -- so is the suspicious order report that you get every day, do you consider that a useful tool for detecting potential diversion? A. I do not.").

### B. Submission of Additional Suspicious Order Reports by Distributors Would Not Likely Have Helped Combat Diversion

205. It is unlikely that the submission of more suspicious order reports by distributors would have helped DEA combat diversion.[440] Distributors did not contribute to diversion by not submitting more suspicious order reports, particularly when orders were being blocked.[441] Reporting suspicious orders to DEA was unlikely to prevent diversion during the height of the crisis, and failing to report suspicious orders to DEA likely does not contribute to diversion.[442] That is because the simple fact that an order meets the regulatory definition of a suspicious order does not mean that order will be diverted.[443] DEA largely failed to review and use the suspicious

[440] Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. You'd agree that not reporting the suspicious order is not what causes diversion? A. That's correct."); Boggs Tr. (Jan. 17, 2019) at 315:8-15 ("Q. [I]n five years, none of these omits were reported to the DEA, correct? A. You asked me if we were maintaining effective controls by this document that you -- you created, and I'm saying that if there were 481 stops, that's exactly maintaining effective controls against diversion. They didn't ship them.").

[441] Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. You'd agree that not reporting the suspicious order is not what causes diversion? A. That's correct."); Boggs Tr. (Jan. 17, 2019) at 315:8-15 ("Q. [I]n five years, none of these omits were reported to the DEA, correct? A. You asked me if we were maintaining effective controls by this document that you -- you created, and I'm saying that if there were 481 stops, that's exactly maintaining effective controls against diversion. They didn't ship them.").

[442] Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. … You'd agree that not reporting the suspicious order to DEA is not what causes diversion? A. That's correct."); Boggs Tr. (Jan. 17, 2019) at 315:8-15 ("Q. [I]n five years, none of these omits were reported to the DEA, correct? A. You asked me if we were maintaining effective controls by this document that you -- you created, and I'm saying that if there were 481 stops, that's exactly maintaining effective controls against diversion. They didn't ship them.").

[443] Boggs Tr. (Jan. 17, 2019) at 97:14-98:2 ("Q. [S]uspicious orders can lead you to a suspicious customer, true? … A. Without learning more about the customer, no. … There is an assumption that a suspicious order equals a suspicious customer, and that is very misplaced from my experience."); Ashley Tr. (Mar. 15, 2019) at 147:8-11 ("Q. Based on your experience, would you agree that there might be situations where an order is of an unusual size, but the order is not suspicious? A. Yes.").

order reports in a manner that would identify potential diversion.[444] DEA did not typically rely on suspicious order reports from distributors to identify and investigate potential diversion.[445] Finally, DEA had access to complete report information through its ARCOS database.

### C. ARCOS Provided DEA Extensive Information

#### 1. Background on ARCOS

206. The Automation of Reports and Consolidated Order System, which is commonly known as "ARCOS," is an "automated, comprehensive drug reporting system."[446] Manufacturers and distributors are required by the CSA to report their controlled substances transactions to DEA.[447] Manufacturers and distributors are required to report all transactions involving Schedule I and Schedule II substances and transactions involving certain Schedule III

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[444] Wright Tr. (Feb. 28, 2019) at 84:9-21 ("Q. And I believe you testified before, in your personal experience reviewing these Excessive Sales Reports, that half to three-quarters of them sometimes went into the trash can; is that right? A. Yes."); Wright Tr. (US v. $463,497.72) at 47:8-49:5 ("Q. It won't just be filed away in a drawer? A. That was the problem with the Excessive Purchase System. It was under the Suspicious Order System. Q. Whose fault was that? Is that the distributor's fault or the DEA's fault? A. That would have been the DEA's fault. Well, no. Let me -- let me reel some of that back in. … I would look through -- again, I had a ton of paper, and I would say half to three-quarters of that went in the trash can. It was meaningless. … Q. You're not suggesting that H.D. Smith was dumping paper on the DEA? A. No, sir. No, sir. No, sir. Not at all. Q. Okay. A. I would just get a volume of paper.").

[445] Wright Tr. (Feb. 28, 2019) at 84:9-21 ("Q. And I believe you testified before, in your personal experience reviewing these Excessive Sales Reports, that half to three-quarters of them sometimes went into the trash can; is that right? A. Yes."); Wright Tr. (US v. $463,497.72) at 47:8-49:5 ("Q. It won't just be filed away in a drawer? A. That was the problem with the Excessive Purchase System. It was under the Suspicious Order System. Q. Whose fault was that? Is that the distributor's fault or the DEA's fault? A. That would have been the DEA's fault. Well, no. Let me -- let me reel some of that back in. … I would look through -- again, I had a ton of paper, and I would say half to three-quarters of that went in the trash can. It was meaningless. … Q. You're not suggesting that H.D. Smith was dumping paper on the DEA? A. No, sir. No, sir. No, sir. Not at all. Q. Okay. A. I would just get a volume of paper.").

[446] DEA Website, Automation of Reports and Consolidated Orders System (ARCOS), *available at* https://www.deadiversion.usdoj.gov/arcos/index.html.

[447] DEA Website, Automation of Reports and Consolidated Orders System (ARCOS), *available at* https://www.deadiversion.usdoj.gov/arcos/index.html.

narcotics and select Schedule IV substances.[448] Through ARCOS, DEA monitors the flow of opioids as they travel from the manufacturer to the distributor to hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions.[449]

**2. ARCOS Provides DEA with Comprehensive Reports**

207. ARCOS is a robust system that provides DEA with large amounts of information.[450] Using ARCOS, DEA knows how many dosage units that a manufacturer sells.[451] DEA also knows through ARCOS how many dosage units that a distributor has distributed to a registrant, such as hospitals and pharmacies.[452] DEA can also generate reports that show controlled substance distribution in grams and dosage units.[453]

208. DEA is able to run a wide-range of reports using the ARCOS data submitted by manufacturers and distributors. Using ARCOS data submitted by manufacturers and distributors, DEA could create reports comparing the distribution of controlled substances of a particular state to the national average.[454] DEA could also run reports using ARCOS that show:

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[448] DEA Website, Automation of Reports and Consolidated Orders System (ARCOS), *available at* https://www.deadiversion.usdoj.gov/arcos/index.html.

[449] DEA Website, Automation of Reports and Consolidated Orders System (ARCOS), *available at* https://www.deadiversion.usdoj.gov/arcos/index.html.

[450] Wright Tr. (Mar. 4, 2019) at 538:3-10; Rannazzisi Tr. (Apr. 26, 2019) at 23:22-24:15.

[451] Wright Tr. (Mar. 4, 2019) at 538:12-14 ("Q. ARCOS tells you how many pills a manufacturer makes, right? A. How many they sell, yes.").

[452] Wright Tr. (Mar. 4, 2019) at 538:16-19 ("Q. … ARCOS tells you how many pills have been distributed by a distributor to a pharmacy, doesn't it? A. Correct.".

[453] Wright Tr. (Mar. 4, 2019) at 539:5-8 ("Q. And using ARCOS, DEA can generate statistical reports showing drug distribution in grams and dosage units. A. Correct.").

[454] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation, at 14, 17, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf.

- States having an above average distribution of controlled substances compared to other states and the national average;[455]
- Counties having an above average distribution of controlled substances compared to other counties in the state and the national average;[456]
- The number of dosage units purchased by a pharmacy in a particular state. DEA could then compare the number of dosage units purchased by that pharmacy to the average pharmacy purchases in that state and the national average;[457]
- The number of dosage units supplied by each distributor to a pharmacy;[458] and
- The top doctors purchasing a particular controlled substance nationwide.[459]

209. With ARCOS data at its fingertips, DEA had the tools it needed to identify and investigate suspicious pharmacies. Through ARCOS, DEA also had the tools to monitor

[455] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation, at 19, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf.

[456] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation, at 21, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf.

[457] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation, at 24, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf; Wright Tr. (Mar. 4, 2019) at 542:19-24 ("Q. And ARCOS reports can be generated to show the number of dosage units dispensed by a single pharmacy and compared that -- compare that to average pharmacy purchases in the state and across the United States; isn't that true? A. Yes, it can.").

[458] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation, at 26, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf; Wright Tr. (Mar. 4, 2019) at 542:25-543:6 ("Q. And ARCOS reports can be generated to show the number of dosage units supplied by each distributor to a single pharmacy; isn't that true? … A. Yes, sir.").

[459] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation, at 25, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf.

excessive distribution of opioids to a particular town, county, or state. DEA has been able to run these types of reports using ARCOS data since at least 2005.[460]

### 3. DEA Failed to Use ARCOS Until 2005

210. DEA, however, did not use ARCOS data until 2005 to identify potentially suspicious pharmacies. Former DEA employee Kyle Wright testified that he did not start analyzing ARCOS data until 2005.[461] DEA relied on ARCOS data to identify certain potentially suspicious pharmacies during the Distributor Initiative.[462] DEA did not need suspicious order reports from distributors to identify potentially suspicious pharmacies during the Distributor Initiative.[463]

### 4. Distributors Did Not Have Access to ARCOS Data and Now Only Have Limited Access

211. Distributors did not have access to the extensive reports available using ARCOS data.[464] Distributors only had access to their own data. Distributors did not have access to the ARCOS data of other distributors or the ARCOS data submitted by manufacturers.[465] A

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[460] Wright Tr. (Feb. 28, 2019) at 249:3-13.

[461] Wright Tr. (Mar. 4, 2019) at 536:1-9 (Q. You … first started to analyze ARCOS data beginning around 2005; isn't that correct? … A. Yes, sir. Q. And that -- that's when you began working on the distributor initiative? A. Yes, sir.").

[462] Wright Tr. (Mar. 4, 2019) at 543:23-544:6 ("Q. [W]hen you were preparing for the distributor briefings … you were using these ARCOS reporting tools to identify pharmacies having extraordinarily large prescriptions in narcotics, and you present that data to the distributors, correct? A. Yes, sir.").

[463] Wright Tr. (Mar. 4, 2019) at 544:7-11 ("Q. You didn't -- you didn't need distributors' suspicious order reports to do that analysis [of pharmacies with extraordinarily large prescriptions in narcotics], did you? … A. No, sir.".

[464] Wright Tr. (Mar. 4, 2019) at 554:11-25; Rannazzisi Tr. (Apr. 26, 2019) at 25:6-20.

[465] Wright Tr. (Mar. 4, 2019) at 554:11-25 ("Q. But DEA, up until 2018, did not permit other distributors to see the ARCOS data so that they could determine how much of a single -- of -- of a -- of a controlled substance was being shipped into a pharmacy by another distributor; isn't that correct? … A. Yes, sir."); Rannazzisi Tr. (Apr. 26, 2019) at 25:6-20 ("Q. Registrants did not have access to ARCOS data during you -- the time you led the Office of Diversion Control,

distributor could only rely on its own data, and a distributor did not have visibility into whether other distributors were supplying a particular pharmacy with controlled substances.[466] DEA understood that distributors attempting to identify potential diversion would benefit from access to information other than only the distributor's own sales data and customer observations.[467] DEA also understood that access to ARCOS data would have helped distributors identify potential diversion.[468]

212. It was not until February 2018, however, that DEA agreed to share limited ARCOS data with registrants.[469] Prior to 2018, registrants had requested access from DEA to ARCOS data to help identify potential diversion, but DEA declined to provide access to greater information.[470] It was only in 2018 that DEA announced that it would permit limited access to

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correct? A. They had access to their own data that they submitted to ARCOS. But no, not other.").

[466] Wright Tr. (Mar. 4, 2019) at 554:11-25 ("Q. But DEA, up until 2018, did not permit other distributors to see the ARCOS data so that they could determine how much of a single -- of -- of a -- of a controlled substance was being shipped into a pharmacy by another distributor; isn't that correct? … A. Yes, sir."); Rannazzisi Tr. (Apr. 26, 2019) at 25:6-20 ("Q. Registrants did not have access to ARCOS data during you -- the time you led the Office of Diversion Control, correct? A. They had access to their own data that they submitted to ARCOS. But no, not other.").

[467] June Howard ("Howard") Tr. (Apr. 25, 2019) at 29:23-30 ("Q. DEA understood that distributors trying to identify potential diversion would benefit from access to more information than just their own sales data and customer observations, right? …. A. Yes.").

[468] Howard Tr. (Apr. 25, 2019) at 44:23-45:4 ("Q. Would you agree that ARCOS data would have been helpful to distributors to identify potential diversion? … A. Yes.").

[469] DEA Press Release, "DEA Creates New Resource to Help Distributors Avoid Oversupplying Opioids," (Feb. 14, 2018), *available at* https://www.dea.gov/press-releases/2018/02/14/dea-creates-new-resource-help-distributors-avoid-oversupplying-opioids.

[470] Rannazzisi Tr. (Apr. 26, 2019) at 26:3-13 ("Q. Registrants requested ARCOS data from DEA at various times, but DEA declined to share it, correct? … A. Just answering the question in order -- Q. Yes. A. -- registrants have requested access to ARCOS -- for that data. And they have been declined, yes.").

ARCOS data as part of its efforts to work more collaboratively with distributors and manufacturers.[471]

213. Starting in February 2018, DEA allowed manufacturers and distributors to view the number of suppliers who sold a particular controlled substance to a customer within the previous six months.[472] DEA announced in 2019 that it would allow further access to registrants.[473] DEA described the new access granted to registrants as a tool to "more effectively identify potential illicit drug diversion and combat the opioid epidemic."[474] Manufacturers and distributors can now "view and download the number of distributors and the amount (anonymized data in both grams and dosage units)" that each unnamed supplier "sold to a prospective customer" in the last six months.[475]

[471] DEA Press Release, "DEA Creates New Resource to Help Distributors Avoid Oversupplying Opioids," (Feb. 14, 2018), *available at* https://www.dea.gov/press-releases/2018/02/14/dea-creates-new-resource-help-distributors-avoid-oversupplying-opioids.

[472] DEA Press Release, "DEA Creates New Resource to Help Distributors Avoid Oversupplying Opioids," (Feb. 14, 2018), *available at* https://www.dea.gov/press-releases/2018/02/14/dea-creates-new-resource-help-distributors-avoid-oversupplying-opioids.

[473] DEA Press Release, "DEA Announces Enhanced Tool for Registered Drug Manufacturers and Distributors to Combat Opioid Crisis," (Feb. 26, 2019), *available at* https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and.

[474] DEA Press Release, "DEA Announces Enhanced Tool for Registered Drug Manufacturers and Distributors to Combat Opioid Crisis," (Feb. 26, 2019), *available at* https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and.

[475] DEA Press Release, "DEA Announces Enhanced Tool for Registered Drug Manufacturers and Distributors to Combat Opioid Crisis," (Feb. 26, 2019), *available at* https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and.

## XIII. Distributors Do Not Possess DEA's Law Enforcement Powers

### A. Distributors Have Limited Information

214. Distributors only have access to limited amounts of information to determine if an order is suspicious or if a customer is potentially diverting controlled substances.[476] DEA, for example, has a policy that prohibits DEA investigators from informing a distributor if DEA was investigating a pharmacy customer of that distributor.[477] DEA would not inform a distributor that it was investigating a pharmacy customer even if DEA suspected the pharmacy of ongoing criminal conduct.[478] DEA also has access to ARCOS data that provides DEA with large amounts of information about controlled substance transactions as I describe above. DEA has acknowledged that access to ARCOS data would have been a helpful tool for distributors.[479]

215. Distributors also have limited access to information about whether other distributors cut off a pharmacy customer.[480] DEA stopped sending notices to distributors that

[476] Howard Tr. at 29:23-30:6 ("Q. DEA understood that distributors trying to identify potential diversion would benefit from access to more information than just their own sales data and customer observations, right? … A. Yes.").

[477] Rafalski Trial Tr. (US v. $463,497.72) at 506:6-15 ("A. Well, the DEA has a policy that prohibits DEA investigators from calling and telling people, distributors or any person handling controlled substances, whether or not to distribute a drug or not to distribute. The same premise would be with the pharmacy. We would never tell a pharmacist not to fill a prescription or to fill a prescription, and that's DEA policy. Q. Even if you're aware of ongoing criminal conduct involving that pharmacy? A. Yes.").

[478] Rafalski Trial Tr. (US v. $463,497.72) at 506:10-15 ("…A. We would never tell a pharmacist not to fill a prescription or to fill a prescription, and that's DEA policy. Q. Even if you're aware of ongoing criminal conduct involving that pharmacy? A. Yes.").

[479] Howard Tr. at 44:23-45:4 ("Q. Would you agree that ARCOS data would have been helpful to distributors to identify potential diversion? … A. Yes.").

[480] Howard Tr. at 29:23-30:6 ("Q. DEA understood that distributors trying to identify potential diversion would benefit from access to more information than just their own sales data and customer observations, right? … A. Yes.").

another distributor terminated a particular pharmacy customer in 2007.[481] After 2007, DEA would not inform a distributor if another distributor terminated a pharmacy as a customer. DEA stopped informing distributors of a pharmacy's termination "because diversion investigators in the field expressed concern about the notification."[482] The notices were stopped by DEA because diversion investigators had concerns that the individuals on the notices that DEA sent to distributors "were legitimate pharmacies or doctors and needed their product for legitimate medical purposes."[483] DEA had concerns that the pharmacies cut off by distributors "had legitimate purposes for ordering product and they should not be blacklisted."[484] DEA also stopped notifying distributors of the terminations because of "the threat of potential litigation."[485] Therefore, it was DEA's policy not to tell a distributor that the distributor should

[481] Howard Tr. at 45:9-13 ("Q. And do you know when the DEA stopped sending termination notices to distributors? A. Based on the DEA records that I reviewed, it appears that it ceased in December 2007.").

[482] Howard Tr. at 47:2-13 ("Q. Why did DEA stop sending the termination notices to distributors? A. Based on my review of the DEA records, it appears the notification process ceased because diversion investigators in the field expressed concern about the notification ….").

[483] Howard Tr. at 47:2-18 ("… A. Based on my review of the DEA records, it appears the notification process ceased because diversion investigators in the field expressed concern about the notification, and individuals on the listing were legitimate pharmacies or doctors and needed their product for legitimate medical purposes. …").

[484] Howard Tr. at 47:2-18 ("Q. Why did DEA stop sending the termination notices to distributors? A. Based on my review of the DEA records, it appears the notification process ceased because diversion investigators in the field expressed concern about the notification, and individuals on the listing were legitimate pharmacies or doctors and needed their product for legitimate medical purposes. Also, the threat of potential litigation. Q. And what were the concerns of the diversion investigators? A. That registrants that were identified had legitimate purposes for ordering product and they should not be blacklisted.").

[485] Howard Tr. at 31:3-10 ("Q. You would agree that the more information the distributor has on the pharmacy, the more helpful that would be to prevent diversion, correct. … A. Yes."); Howard Tr. at 47:2-18 ("Q. Why did DEA stop sending the termination notices to distributors? A. Based on my review of the DEA records, it appears the notification process ceased because diversion investigators in the field expressed concern about the notification, and individuals on the listing were legitimate pharmacies or doctors and needed their product for legitimate medical purposes. Also, the threat of potential litigation.").

not make sales to a particular pharmacy customer even though DEA recognized that distributors would benefit from having access to greater information.[486]

216. It is also important to remember that distributors do not have access to information about the relationship between a particular prescriber and his or her patients. Distributors, for example, do not have access to a patient's medical records.[487] DEA, however, can obtain a patient's medical records through subpoena, which the distributor cannot.[488]

217. Distributors lack many of sources of information that DEA uses to determine if a pharmacy or prescriber is engaged in diversion. Information on sales transactions involving controlled substances is often not enough information to determine if a doctor or pharmacy is engaged in a criminal diversion scheme.[489]

**B. Distributors Do Not Possess Law Enforcement Powers**

218. Distributors lack the law enforcement powers held by DEA. Distributors cannot serve search warrants on a pharmacy, but DEA possesses the power to serve search warrants on

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[486] Rannazzisi Tr. (Apr. 26, 2019) at 44:1-10; Howard Tr. at 29:23-30:6 ("Q. DEA understood that distributors trying to identify potential diversion would benefit from access to more information than just their own sales data and customer observations, right? … A. Yes."); Howard Tr. at 31:3-10 ("Q. You would agree that the more information the distributor has on the pharmacy, the more helpful that would be to prevent diversion, correct. … A. Yes."); Howard 44:23-45:8 ("Q. Would you agree that ARCOS data would have been helpful to distributors to identify potential diversion? … A. Yes. Q. Now, DEA stopped sending termination notices to distributors, correct? A. Correct.").

[487] Rafalski Trial Tr. (US v. $463,497.72) at 508:5-9 ("Q. There were also some medical records you reviewed, correct? A. Yes, sir. Q. And those aren't available to H.D. Smith? A. That's correct."); Boggs Tr. (Jan. 17, 2019) at 360:9-15 ("Q. Why not? A. We don't see the prescription. We're prohibited by law under HIPAA from knowing anything about the patient or any consultation between the patient and the doctor, and we don't have access to prescription -- the prescription itself.").

[488] Rafalski Trial Tr. (US v. $463,497.72) at 508:5-9.

[489] Rafalski Trial Tr. (US v. $463,497.72) at 511:2-14; Howard Tr. at 29:23-30:6 ("Q. DEA understood that distributors trying to identify potential diversion would benefit from access to more information than just their own sales data and customer observations, right? … A. Yes.").

pharmacies that are suspected of diversion.[490] DEA also does not share information that it learns from a search warrant with distributors.[491]

219. Another law enforcement power possessed by DEA is its ability to force a pharmacy to provide DEA with surveillance tapes.[492] A distributor is unable to require a pharmacy to turn over surveillance tapes.

### C. Distributors Cannot Police the Closed System of Distribution

220. DEA is required by the CSA to oversee the closed loop system of distribution, and DEA is granted the authority to police the closed loop system of distribution. Distributors lack the information and law enforcement powers needed to police the closed loop system of distribution. The CSA provides DEA with seven mechanisms to police the closed loop system of distribution according to Mr. Rannazzisi's testimony to Congress.[493] The seven powers granted

[490] Rafalski Trial Tr. (US v. $463,497.72) at 504:24-505:3 ("Q. One of the ways you used [to find out about criminal activity] was, you served search warrants? A. Yes, sir. Q. And those were pretty extensive, correct? A. Yes, sir.").

[491] Rafalski Trial Tr. (US v. $463,497.72) at 505:25-506:2 ("Q. And you never provided the results of those [warrants] to H.D. Smith? A. That's correct.").

[492] Rafalski Trial Tr. (US v. $464,497.72) at 506:16-22 ("Q. You obtained surveillance tapes from Safescript? A. Yeah, but I would characterize those more as security tapes, if you are referring to the ones that were seized from the interior as part of Safescript's security program. Q. And you never provided the results of -- the review of those tapes to H.D. Smith, did you? A. No, sir.").

[493] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

to DEA are scheduling, registration, quotas, records and reports, import and export authorizations, security and investigational authority.[494] Mr. Rannazzisi explained that:

> These mechanisms allow DEA to monitor and regulate a controlled substance and its movement: in the case of the most potentially dangerous drugs, in Schedule II, we register all persons who handle them; we inspect the documentation of their distribution; we control their import and export; and we control the amount produced, bought, sold, and otherwise transferred.[495]

221. Manufacturers, distributors, pharmacies, and doctors are required to register with DEA in order to handle controlled substances.[496] Those entities and prescribers are unable to lawfully handle or prescribe opioids without being registered with DEA.[497] DEA holds the authority to suspend or revoke a registrant's controlled substance registration.[498] If DEA revokes or suspends a registrant's registration, the registrant is unable to conduct transactions involving controlled substances.[499]

222. In contrast, if a distributor terminates a pharmacy as a customer, that pharmacy can still purchase controlled substances from other distributors, and DEA does not inform

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[494] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[495] Statement of Joseph Rannazzisi, House Hearing on Prescription Drug Abuse: What is being done to address this new drug epidemic? (July 26, 2006), at 68, *available at* https://www.govinfo.gov/content/pkg/CHRG-109hhrg35338/pdf/CHRG-109hhrg35338.pdf.

[496] Rannazzisi Tr. (Apr. 26, 2019) at 21:15-22:10 (describing that manufacturers, distributors, pharmacies, and doctors must all be registered in order to lawfully handle opioids).

[497] Rannazzisi Tr. (Apr. 26, 2019) at 21:15-22:10 (describing that manufacturers, distributors, pharmacies, and doctors must all be registered in order to lawfully handle opioids).

[498] Rannazzisi Tr. (Apr. 26, 2019) at 22:11-14 ("Q. Now, DEA can, when it determines it is legally appropriate, suspend or revoke a DEA registration. A. Yes.").

[499] Rannazzisi Tr. (Apr. 26, 2019) at 22:11-24.

distributors if a pharmacy is cut off by another distributor.[500] The only way to ensure that a suspicious pharmacy or prescriber is not able to handle controlled substances is for DEA to revoke or suspend the registration of that pharmacy or prescriber. It is DEA's responsibility to ensure that registrants comply with the CSA and its regulations.[501]

223. Distributors do not control the amount of opioids that enter the closed loop system of distribution. It is DEA that sets the quotas that limit the amount of opioids that enter into the closed loop system.[502] The quota set by DEA reflects the estimated legitimate medical, scientific, research, and industrial needs of the US.[503] DEA continually raised opioid quotas between 2000 and 2015.[504] By increasing opioid quotas which are required by regulation to reflect legitimate medical need, DEA told registrants that greater amounts of opioids should be available to treat patients' legitimate medical needs.

224. DEA also told registrants through other channels that the increasing amounts of opioids were for legitimate medical purposes. DEA stated publicly that "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate

[500] Howard Tr. at 45:9-13 ("Q. And do you know when the DEA stopped sending termination notices to distributors? A. Based on the DEA records that I reviewed, it appears that it ceased in December 2007.").

[501] Rannazzisi Tr. (Apr. 26, 2019) at 23:3-13 ("A. It's DEA's responsibility to ensure that the registrant population is complying with the code of federal regulations 21 C.F.R. and also 21 USC, United States code.").

[502] Rannazzisi Tr. (Apr. 26, 2019) at 30:12-22 ("Q. DEA established quotas for controlled substances for each year, didn't they. A. Yes, sir. Q. Quotas are set based on the estimated medical scientific research and industrial needs of the United States? A. Yes, sir. Q. Your office, the Office of Diversion Control, was responsible for setting quotas? A. Yes, sir.").

[503] Rannazzisi Tr. (Apr. 26, 2019) at 30:12-19.

[504] Rannazzisi Tr. (Apr. 26, 2019) at 31:8-10 ("Q. And quota levels for opioids constantly increased under your watch, correct? A. Yes, sir.").

medical purposes."[505] DEA also said "the agency recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice."[506] In the same statement, DEA also said "[i]t would be a disservice to many patients if exaggerated statements regarding the likelihood of a DEA investigation resulted in physicians mistakenly concluding that they must scale back their patients' use of controlled substances to levels below that which is medically appropriate."[507]

225. DEA also announced in a joint statement with twenty-one health groups that "[u]ndertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death."[508] DEA said "[e]ffective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively."[509] DEA then stated "[f]or many patients, opioid analgesics—when used as recommended by established pain management guidelines—are the

[505] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719 (Sept. 6, 2006), *available at* https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/E6-14517.pdf.

[506] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,720 (Sept. 6, 2006), *available at* https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/E6-14517.pdf.

[507] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,720 (Sept. 6, 2006), *available at* https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/E6-14517.pdf.

[508] Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act (Oct. 23, 2001), *available at* https://www.deadiversion.usdoj.gov/pubs/advisories/painrelief.pdf.

[509] Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act (Oct. 23, 2001), *available at* https://www.deadiversion.usdoj.gov/pubs/advisories/painrelief.pdf.

most effective way to treat their pain, and often the only treatment option that provides significant relief."[510]

226. As discussed above, distributors do not have the ability to determine the legitimacy of a prescription for opioids because distributors do not possess the medical expertise and have no access to information about the prescriber-patient relationship.[511]

## XIV. Response to the Expert Report of James Rafalski

227. I reviewed the expert report of James Rafalski submitted on April 15, 2019, and his deposition testimony.

### A. Mr. Rafalski's Assumption That McKesson Did Not Conduct Due Diligence Is Incorrect

228. Mr. Rafalski's report assumes that McKesson failed to conduct due diligence on potential suspicious orders of controlled substances and, after 2007, that McKesson conducted inadequate due diligence of suspicious orders.[512] In his report, Mr. Rafalski asserts that, "[f]rom at least 1997 to May 2007, there was no due diligence conducted by McKesson regarding potential suspicious orders of controlled substances."[513] Mr. Rafalski also criticizes McKesson's due diligence efforts after May 2007, stating that "while McKesson has had some sort of due diligence program in place since 2007, a review of those programs in practice make[s] clear that for all practical purposes, McKesson's due diligence efforts have fallen short of what is

[510] Joint Statement from 21 Health Organizations and the Drug Enforcement Administration, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act (Oct. 23, 2001), *available at* https://www.deadiversion.usdoj.gov/pubs/advisories/painrelief.pdf.

[511] Boggs Tr. (Jan. 17, 2019) at 360:5-15 ("Q. So does the -- does McKesson's compliance program target overprescribing, as you've just described it? A. It -- it can't.").

[512] Expert Report of James E. Rafalski (Apr. 15, 2019) at 73-74.

[513] Expert Report of James E. Rafalski (Apr. 15, 2019) at 73.

required."[514]

229. Neither of these statements is accurate, and both rest on Mr. Rafalski's incorrect belief that if McKesson cannot produce a document proving diligence, then the diligence never happened.[515] Mr. Rafalski applies his mistaken assumption even for events occurring over 20 years ago. Significantly, the CSA and its regulations do not require McKesson to retain diligence records at all. The CSA and its regulations require only that "inventory and other records" be maintained for two years.[516] In contrast, Mr. Rafalski contends that any records related to suspicious order reports must be maintained "forever"[517] to be in full compliance with 21 C.F.R. § 1301.74(b).

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[514] Expert Report of James E. Rafalski (Apr. 15, 2019) at 74.

[515] Rafalski Tr. (May 13, 2019) at 289:10-24 ("Q. In your report, you come to the opinion that if a distributor's unable to locate a due diligence file, say, from 2006, that no due diligence was done, correct? If you can't put your hands on it today, you make the assumption that nothing was done; is that right? A. Yes, sir. Q. Is it possible that due diligence was done back in 2006 or even earlier, but those records weren't retained? A. Well, my opinion on that matter is if there were no records retained, then there was no due diligence because there's no record of it.").

[516] 21 U.S.C. § 827(b). The CSA does not contain language requiring the retention of suspicious order reports or due diligence files. 21 U.S.C. § 827. The regulations issued under the CSA also only require distributors to retain "inventory and other records" for two years. 21 C.F.R. § 1304.04; Prevoznik Tr. (May 17, 2019) at 1218:17-1219:10 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant. … Q. But there's no requirement that a due diligence file even be maintained, correct? A. Correct. Q. So the two-year rule does not apply to any due diligence files, per se, correct? A. Correct. I was just pointing out that within the regs, there is records for a two-year period."); Rannazzisi Tr. (May 15, 2019) 555:7-11 ("Q. Is there any requirement in the DEA regulations or guidance to maintain due diligence documentation for a certain period of time? A. There's no requirements."). Section 1304.04 does not require distributors to retain suspicious order reports or due diligence files for two years. 21 C.F.R. § 1304.04; Prevoznik Tr. (May 17, 2019) at 1216:8-12.

[517] Rafalski Tr. (May 13, 2019) at 125:11-129:12.

### B. Mr. Rafalski's Assumption That Recent Policy Interpretations Were Always in Place Is Incorrect

230. Although Mr. Rafalski acknowledges that the industry is changing all the time,[518] he purports to apply recently announced DEA guidance and standards retrospectively. For example, Mr. Rafalski applies the methodologies Plaintiffs derive from *Masters Pharmaceuticals*[519] to distributor shipping data from as early as 1996 – years before the *Masters* decision was issued in 2017.[520]

### C. The Five Methodologies That Found Over 90% of Orders Shipped into Cuyahoga and Summit Counties Are Suspicious Contradicts Reality

231. Mr. Rafalski, relying on Dr. McCann's expert report, identifies five different suspicious order methodologies that purport to "identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion."[521] He then concludes that "[e]ach method would have identified a significant volume of orders of opiates…"[522] Specifically, Mr. Rafalski's methodologies identify as suspicious orders up to 92.0% of total dosage units of oxycodone that McKesson distributed to Cuyahoga County between 1996 and 2018; up to 95.5% of total dosage units of oxycodone that McKesson distributed to Summit County from 1996-2018; up to 91.7% of total dosage units of hydrocodone that McKesson distributed to Cuyahoga County between 1996 and 2018; and up to 95.5% of total dosage units of hydrocodone that McKesson distributed to Summit County from 1996-

[518] Rafalski Tr. (May 13, 2019) at 156:11-21 ("Q. … [T]he customers change, the customers' businesses change, the hospitals and the doctors change. All that stuff is constantly changing, correct? … A. It's never a static industry.").

[519] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (2017).

[520] Expert Report of James E. Rafalski (Apr. 15, 2019) at 41, 46.

[521] Expert Report of James E. Rafalski (Apr. 15, 2019) at 40-41.

[522] Expert Report of James E. Rafalski (Apr. 15, 2019) at 41.

2018.[523]

232. Any contention that over 90% of the orders a distributor ships into a county are suspicious orders is inconsistent with my experience as a diversion investigator. It is also contrary to DEA's own public statements and testimony.[524] These methodologies assume that the vast majority of registrants are not acting lawfully. In my experience, the vast majority of registrants act lawfully, and my opinion is confirmed by DEA's public statements and testimony.[525]

**D. Any Lack of Suspicious Order Reports Does Not Contribute to Diversion**

233. I also disagree with Mr. Rafalski's conclusion that McKesson should have submitted more suspicious order reports. For example, Mr. Rafalski states that "[f]or Summit

[523] Expert Report of James E. Rafalski (Apr. 15, 2019) at 41.

[524] Prevoznik Tr. (Apr. 17, 2019) at 401:5-17 ("Q. As to prescription opioids, DEA believes the overwhelming majority of prescribing in America is conducted responsibly? A. Yes, correct. Q. And DEA has stated that 99.5 percent of prescribers do not overprescribe opioids… A. I don't know that we've said 99.5 percent. I've heard the figure 1 to 2 percent."); Prevoznik Tr. (Apr. 17, 2019) at 403:14-19 (Q. So my question for you, the initial question, was, DEA has publicly stated that 99.5 percent of prescribers are not overprescribing, correct? A. Correct."); Testimony of Joseph Rannazzisi, House Hearing on Examining the Growing Problems of Prescription Drugs and Heroin Abuse (Apr. 29, 2014) at 76 ("I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing."), *available at* https://www.govinfo.gov/content/pkg/CHRG-113hhrg90923/pdf/CHRG-113hhrg90923.pdf; Testimony of Robert Patterson (Acting Administrator, DEA), House Hearing on Challenges and Solutions in the Opioid Crisis (May 8, 2018), at 32 ("But I go back to the fact that I look at the vast majority of doctors: 99.99 percent are all trying to do right by their patients."), *available at* https://www.govinfo.gov/content/pkg/CHRG-115hhrg32941/pdf/CHRG-115hhrg32941.pdf.

[525] Ashley Tr. at 329:14-22 ("Q. In you, frankly, remarkable career of rising from a secretary all the way up to an executive at DEA, isn't it the case, Ms. Ashley, that the vast majority of registrants with whom you dealt were trying to comply with the CSA and implementing regs?... A. I agree with that, yes."); September 27, 2006 Dear Registrant Letter (MCKMDL00478906 at -8907 ("DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion.").

and Cuyahoga Counties, McKesson failed to report a single suspicious order from May 2008 to July 31, 2013."[526] But Mr. Rafalski fails to acknowledge that McKesson submitted ARCOS data to DEA during the period. As I discussed above, ARCOS data provides DEA with extensive information about distributors' transactions involving controlled substances. DEA could run many different types of reports using ARCOS data, including the number of dosage units purchased by a pharmacy and the number of dosage units supplied by each distributor to a pharmacy.[527]

234. Mr. Rafalski and I can agree, however, that not providing suspicious order reports likely does not cause diversion of controlled substances.[528] Instead, according to Mr. Rafalski, blocking a suspicious order is what prevents diversion.[529] As I discussed above, McKesson has automatically blocked all orders above the threshold set under the CSMP since April 2008.[530]

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[526] Expert Report of James E. Rafalski (Apr. 15, 2019) at 79.

[527] Kyle Wright, "ARCOS, Automation of Reports and Consolidated Orders System," Presentation at 24, 26, *available at* https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2011/wright.pdf; Wright Tr. (Mar. 4, 2019) at 542:19-543:11 ("Q. And ARCOS reports can be generated to show the number of dosage units supplied by each distributor to a single pharmacy; isn't that true? … A. Yes, sir. Q. Now, [DEA has] been able to generate these types of reports using ARCOS since at least 2005, correct? A. Yes, sir.").

[528] Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. You'd agree that not reporting the suspicious order to DEA is not what causes diversion? A. That's correct.").

[529] Rafalski Tr. (May 13, 2019) at 370:25-371:2 ("Q. Blocking the order of the opioid pills before shipment is what prevents diversion from occurring, correct? A. Yes, sir."); Rafalski Tr. (May 13, 2019) at 371:20-23 ("Q. You'd agree that not reporting the suspicious order is not what causes diversion? A. That's correct.").

[530] McKesson Controlled Substance Monitoring Program, 2008 (MCKMDL00409301 at -9306); Walker Tr. at 381:8-21.

## XV. Response to the Expert Reports of Seth Whitelaw

235. I reviewed the expert report of Seth Whitelaw submitted on April 15, 2019, and his deposition testimony.

### A. DEA Does Not Use or Rely on the Federal Sentencing Guidelines When Evaluating Suspicious Order Monitoring Programs

I understand that Mr. Whitelaw relies on the Federal Sentencing Guidelines for Organizations to evaluate the compliance programs of DEA registrants for suspicious order monitoring.[531] Federal Sentencing Guidelines are used by courts after verdict in a federal criminal case.[532] Compliance professionals with DEA experience understand that the Federal Sentencing Guidelines are not used to evaluate suspicious order monitoring programs under the CSA. The Federal Sentencing Guidelines are not used by DEA Diversion Investigators when they evaluate suspicious order monitoring programs of registrants.[533] In addition, DEA Diversion Investigators are not trained to rely on the Federal Sentencing Guidelines when evaluating registrants' suspicious order monitoring programs.[534]

[531] Expert Report of Seth Whitelaw (Apr. 15, 2019) at 7.

[532] Prevoznik Tr. (May 17, 2019) at 1201:20-25 ("Q. Are you aware that the Federal Sentencing Guidelines are used by courts in sentencing after a verdict in a criminal case?...A. Yes.").

[533] Prevoznik Tr. (May 17, 2019) at 1202:2-11 ("Q. The DEA doesn't use the Federal Sentencing Guidelines to evaluate registrants' suspicious order monitoring programs, correct?...A. Yes. Correct. Q. Correct that they do not? A. Do not.").

[534] Prevoznik Tr. (May 17, 2019) at 1202:13-20 ("Q. Now, when you were training diversion investigators, did you ever instruct diversion investigators to rely on the Federal Sentencing Guidelines to evaluate registrants' suspicious order monitoring programs?...A. No.").

Dated: June 6, 2019

Carlos Aquino 6/6/2019